

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
SONIA URRIOLA,
Plaintiff,

07-cv-10591 (RJH)(DFE)

- against -

NOTICE OF MOTION

GUIDANT CORPORATION et al,
Defendants.
-----X

PLEASE TAKE NOTICE that, upon the annexed affirmation of Louis J. Schepp, dated December 26, 2007, and exhibits annexed thereto, the undersigned will move this Court by Judge Richard J. Howell, at the Courthouse located at 500 Pearl Street, New York, NY, on a date and at a time to be determined by the Court, for an Order pursuant to 28 U.S.C. § 1447(c) remanding the within action to the New York County, Supreme Court for the State of New York, and for such other and further relief as to the Court may seem just and proper.

Dated: Brooklyn, New York

December 26, 2007

Bonina & Bonina, P.C.
By _____s/_____
Louis J. Schepp(LS4555)
Attorneys for Plaintiffs
Suite 1800
16 Court Streets
Brooklyn, NY 11241
(718) 522-1786

TO: Kimberly S. Penner (by ECF)
McCarter & English, L.L.P. (NYC)
Attorneys for Guidant Corporation,
Guidant Sales Corporation and
Boston Scientific Corporation
245 Park Avenue
New York, NY 10167
(212) 609-6804

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Jay A. Rappaport (by Mail)
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Beth Israel Medical Center and
Phillips Ambulatory Care Center
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December 26, 2007

McCarter & English, LLP
4 Gateway Center
100 Mulberry Street
P.O. Box 562
Newark, New Jersey 07102

Aaronson Rappaport Feinstein & Deutsch, LLP
757 3rd Avenue
New York, New York 10017
Attention: Jay A. Rappaport, Esq.

Attention: Kimberly S. Penner, Esq.

Re: Sonia Urriola v. Guidant Corporation, et. al.
U.S. DC Docket No.: 2007 Civ. 10591 (RJH)

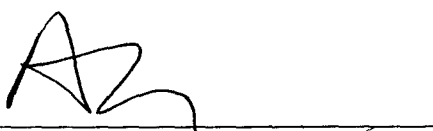
Dear Counsel:

Enclosed is a copy of the Plaintiff's Motion to Remand.

Should you have any questions or wish to discuss this matter, please do not hesitate contacting me at my office.

Very truly yours,

Bonina & Bonina, P.C.

By: 
Andrea E. Bonina, Esq.

AB:mg

Enc.

I, the undersigned, am an attorney admitted to practice in the courts of New York, and

☐
Attorney's
Certification

certify that the annexed
has been compared by me with the original and found to be a true and complete copy thereof.
say that: I am the attorney of record, or of counsel with the attorney(s) of record, for
. I have read the annexed

☐
Attorney's
Verification
By
Affirmation

know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on
information and belief, and as to those matters I believe them to be true. My belief, as to those matters therein not stated on
upon knowledge, is based on the following. By a review of a file maintained is my office.

The reason I make this affirmation instead of Plaintiff is Plaintiff resides in a County other than the one in which I maintain my office.
affirm that the foregoing statements are true under penalties of perjury.

Dated:

STATE OF NEW YORK, COUNTY OF

ss:

(Print signer's name below signature)

being sworn says: I am

☐
Individual
Verification

in the action herein; I have read the annexed
know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on
information and belief, and as to those matters I believe them to be true.
the of

☐
Corporate
Verification

a corporation, one of the parties to the action; I have read the annexed
know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged
on information and belief, and as to those matters I believe them to be true.
My belief, as to those matters therein not stated upon knowledge, is based on the following:

Sworn to before me on

, 19

(Print signer's name below signature)

STATE OF NEW YORK, COUNTY OF KINGS

ss.:

Maria Giamundo, being sworn says: I am not a party to the action, am over the age of 18 years of age and reside at Brooklyn, New York.
On December 26, 2007, I served a true copy of the annexed **MOTION TO REMAND** in the following manner:

☒
Service
by Mail

by mailing the same in a sealed envelope, with postage prepaid thereon, in a post-office or official depository of the U.S.
Postal Service within the State of New York, addressed to the last know address of the addressee(s) as indicated below:

☐
Personal
Service

by delivering the same personally to the persons and at the addresses indicated below:

☐
Service by
Electronic
Means

by transmitting the same to the attorney by electronic means to the telephone number or other station or other limitation designated by the
attorney for that purpose. In doing so I received a signal from the equipment of the attorney indicating that the transmission was received, and
mailed a copy of same to that attorney, in a sealed envelope, with postage prepaid thereon, in a post office or official depository of the U.S.
Postal Service within the State of New York, addressed to the last known address of the addressee(s) as indicated below:

☐
Overnight
Delivery
Service

by depositing the same with an overnight delivery service in a wrapper proper addressed. Said delivery was made prior to the
latest time designated by the overnight delivery service for overnight delivery. The address and delivery service are indicated below:

McCarter & English, LLP
Attorneys for Defendants
Guidant Corporation, Guidant Sales Corporation
and Boston Scientific Corporation
4 Gateway Center
100 Mulberry Street
P.O. Box 562
Newark, New Jersey 07102

Aaronson Rappaport Feinstein & Deutsch, LLP
Attorneys for Defendants
Michael Liou, M.D., Beth Israel Medical Center
and Beth Israel Medical Center Phillips
Ambulatory Care Center
757 3rd Avenue
New York, New York 10017

Sworn to before me on December 26, 2007

Sandra Ferrari

SANDRA FERRARI
NOTARY PUBLIC, State of New York
No. 01FE0083290
Qualified in Kings County
Commission Expires November 15, 2009

Maria Giamundo

(Print signer's name below signature)
MARIA GIAMUNDO

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SONIA URRIOLA,

Plaintiff,

-against-

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON SCIENTIFIC CORPORATION, MICHAEL LIOU, M.D., BETH ISRAEL MEDICAL CENTER and BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants.

MOTION TO REMAND

BONINA & BONINA, P.C.

Attorneys for *Plaintiff(s)*

16 Court Street, Suite 1800

Brooklyn, NY 11241

(718) 522-1786

Fax No.: (718) 243-0414

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed documents are not frivolous.

Dated: December 26, 2007

Signature



Print Signer's Name: ANDREA E. BONINA, ESQ.

Service of a copy of the within

is hereby admitted.

Dated:

Attorney(s) for

PLEASE TAKE NOTICE

| | | |
|----------------------|--------------------------|---|
| Check Applicable Box | <input type="checkbox"/> | that the within is a (certified) true copy of an |
| | NOTICE OF ENTRY | entered in the office of the clerk of the within named Court on |
| | <input type="checkbox"/> | that an Order of which the within is a true copy will be presented for settlement to the Hon. |
| | NOTICE OF SETTLEMENT | at one of the judges of the within named Court, |
| | | on 20 , at M. |

Dated:

BONINA & BONINA, P.C.

Attorneys for *Plaintiff(s)*

16 COURT STREET

BROOKLYN, N.Y. 11241

To:

Attorney(s) for

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X

SONIA URRIOLA,
Plaintiff,

07-cv-10591 (RJH)(DFE)

- against -

Affirmation

GUIDANT CORPORATION et al,
Defendants.

-----X

Louis J. Schepp, an attorney duly admitted to practice law before this Courts and pursuant to the F.R.C.P. and local rule, affirms, the following under the penalties of perjury, that:

1. Plaintiff makes the within motion pursuant to 28 U.S.C. §1447(c) to remand the within action to the New York County, Supreme Court for the State of New York.
2. I am an attorney Of Counsel to Bonina and Bonina, attorneys for plaintiff, and as such am fully familiar with the facts and circumstances set forth herein.
3. I submit this affirmation in support of plaintiff's motion to remand this action to State Court. The removal was improper as this action lacks diversity and furthermore, those defendants not represented by McCarthy & English have not joined in the removal, although duly served at the time of the removal
4. This is a personal injury action wherein plaintiff, Sonia Urriola asserts medical malpractice claims against those defendants' not represented by McCarthy & English and products liability claims against those defendants represented by McCarthy & English, all rising out of the implantation of a defective Guidant cardiac defibrillator and the failure to timely treat the medical conditions that arose as a result of the defects in that medical product. (See the complaint contained in exhibit A.)
5. Defendants, represented by McCarthy & English, by notice of removal, served and filed on November 26, 2007 (Exhibit A,) removed this action from the New York County Supreme Court for the State of New York to this Court.

Joinder of Actions

6. Defendants argue at paragraph 11 of the notice of removal that the citizenship of the defendants, not represented by McCarthy & English, should be disregarded for the purpose of determining whether diversity exists or whether 28 U.S.C. §1441(b) applies to preclude removal. These defendants are citizens of New York State which not only defeats diversity in this action where plaintiff is a citizen of New York State but precludes removal in the first instance.

7. The basis for this argument is that it is alleged that these other defendants, who would defeat diversity have been improperly joined. Specifically defendants argue that plaintiff “has improperly joined the medical negligence claims asserted against the Healthcare Defendants with the product liability claims asserted against the Guidant Defendants.” Notice of removal paragraph 20

8. However the Courts in this Circuit have routinely held that medical malpractice and products liability actions arising out of a device used by the treating physician alleged to have committed malpractice should be tried together.

9. Defendants have cited *In re Rezulin* 168 F.Supp.2d 136 (S.D.N.Y. 2001) to suggest that this is not the case, but a careful reading of *In re Rezulin* supra, reveals that it does not stand for the proposition offered by defendants.

10. In *In re Rezulin* supra at 144 the Court concluded that the joinder of the home healthcare provider was proper. What the Court also found was that actions by one plaintiff “did not arise out of the same transaction or occurrence,” of other plaintiffs and so there was a misjoinder of this plaintiff. *In re Rezulin* supra at 145.

11. In *Whitaker v. American Telecasting, Inc.* 261 F.3d 196, 207 (2nd Cir., 2001) the Second Circuit stated that

“[A] plaintiff may not defeat a federal court's diversity jurisdiction and a defendant's right of removal by merely joining as defendants parties with no real connection with the controversy.”

In order to show that naming a non-diverse defendant is a

“fraudulent joinder” effected to defeat diversity, the defendant must demonstrate, by clear and convincing evidence, either that there has been outright fraud committed in the plaintiff’s pleadings, or that there is no possibility, based on the pleadings, that the plaintiff can state a cause of action against the non-diverse defendant in state court.

“Joinder will be considered fraudulent when it is established ‘that there can be no recovery [against the defendant] under the law of the state on the cause alleged.’ ” (citations omitted/bracket in original).

12. Judge Scheinlin in *Kuperstein v Hoffman-Larouche* 457 F.Supp.2d 467,470 described the burden upon defendants in this manner:

“The defendant seeking removal bears a heavy burden of proving fraudulent joinder, and all factual and legal issues must be resolved in favor of the plaintiff.” To meet this burden, “the defendant must demonstrate, by clear and convincing evidence, either that there has been outright fraud committed in the plaintiff’s pleadings, or that there is no possibility, based on the pleadings that [the] plaintiff can state a cause of action against the non-diverse defendant in state court.” “A court must thus consider the complaint at the time of removal to determine if removal was appropriate.” If even one of the plaintiff’s claims against a non-diverse defendant can survive, the action must be remanded. Finally, apart from fraud, the plaintiff’s motive in joining the non-diverse party is irrelevant, so long as the claim against that party is colorable

13. However it is clear that contrary to the argument of defendants, that the claims against the health care provider defendants in this action, are both viable (which is not denied by defendants) and have a real connection with the controversy asserted against the Guidant defendants because

Products liability and medical malpractice claims arising from the same medical procedure raise common questions

of law and fact. See *Jedraszak v. Intromedix, Inc.*, No. 00 CV 7566, 2004 WL 1497559, at *1 (S.D.N.Y. July 2, 2004); *Hunt*, 2004 WL 502186, at *2; *Rodriguez v. Abbott Laboratories*, 151 F.R.D. 529, 533 (S.D.N.Y.1993). *Clancy v. Zimmer, Inc.* 2007 WL 969237 at *4(W.D.N.Y., 2007.) (Exhibit B)

14. In the context of a motion to add medical malpractice defendants to a pending products liability action, Judge Daniels recognized that “merely because the legal theories asserted in the cases are different does not prevent joinder.” *Jedraszak v. Intromedix, Inc.* 2004 WL 1497559 at *1 (S.D.N.Y., 2004) (Exhibit C) and that “simultaneous litigation ... in two different courts could cause unnecessary expense, conflicting results, a waste of judicial resources, and inconvenience to witnesses who must testify in both trials. *Jedraszak v. Intromedix, Inc.* supra at *2

15. In a similar situation Judge Rakoff recognized that “medical malpractice claims against [a] Hospital ultimately involve some of the same “series” of transactions or occurrences and some of the same “question[s] of fact” as [a] product liability claims against [another] defendant.” *Corchado v Product Design* 2000 WL 134689 at *2 (S.D.N.Y. 2000) (Exhibit D) see also *Dieng v. Smith & Nephew Dyonics, Inc.* 2003 WL 22240748 (S.D.N.Y. 2003) (Exhibit E)

16. In another similar joinder situation, Judge Lasker, in permitting joinder of a medical practice defendant to a products liability action, where the claim against the products defendant involve a separate incident occurring prior to the malpractice, noted

Common questions of law and overlapping questions of fact will arise both with regard to the cause of Leo Wilson's disability and the extent of his damages [and] common questions of law will arise with regard to the relative liability of Famatex and Dr. Schoenbach as alleged consecutive tortfeasors. Therefore, joinder of Dr. Schoenbach is permissible under Rule 20. *Wilson v. Famatex GmbH Fabrik Fuer* 726 F.Supp. 950, 951 (S.D.N.Y., 1989)

17. The answers of the Guidant defendants ((Exhibits F & G) in the Multidistrict litigation to which the Guidant defendants wish to transfer this action, raise various affirmative defenses that are contrary to their position in this action that the medical malpractice action and the product's liability action are so unrelated as to allegedly be misjoined.

18. The seventh affirmative defense of Guidant Corporation (Guidant Sales' answer raises the same affirmative defenses but are numbered differently) sets forth that:

Under the learned intermediary defense, the manufacturer of a prescription medical device is to provide warnings and appropriate information only to the prescribing physician and the medical profession, which act as "learned intermediaries" in determining the use of the product for a particular patient. To the extent Plaintiffs assert that Defendant failed to provide Plaintiffs with adequate warnings regarding the use of the device, any obligation to warn was discharged when adequate warnings were provided to Plaintiffs' or Plaintiffs' Decedents' treating and prescribing physicians. Plaintiffs' claims are also barred by the Sophisticated User Doctrine, or similar applicable laws.

19. Their eighth affirmative defense sets forth that:

Defendant believes, and upon that ground alleges, that Plaintiffs or Plaintiffs' Decedents were advised of the risks associated with the matters alleged in Plaintiffs' Master Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

20. Their ninth affirmative defense sets forth that:

The injuries and damages claimed by Plaintiffs, if any, may have resulted from an intervening cause or causes, and any

action on the part of Defendant was not the proximate or competent producing cause of Plaintiffs' alleged injuries.

21. Obviously one of the intervening causes would be the acts of the malpractice defendants. This ninth affirmative defense fully supports the proposition that the joinder of the medical malpractice claims and products liability claims is proper and that remand is required

22. Their eleventh affirmative defense sets forth that:

Plaintiffs' causes of action are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

23. It thus appears very likely that the Guidant defendants will argue that plaintiff's injuries and damages were caused by others, who will obviously be plaintiff's malpractice defendants.

24. Their fifteenth affirmative defense sets forth that:

Plaintiffs' alleged injuries occurred, if at all, because of circumstances and conditions beyond the control of Defendant.

25. And finally their twenty-sixth affirmative defense sets forth that

At all relevant times, herein, Plaintiffs' or Plaintiffs' Decedents' prescribing physicians were in the position of a sophisticated purchaser, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

26. Thus the Guidant defendants reveal by the nature of their affirmative defenses that plaintiff's claims against the malpractice defendants and the products liability defendants are interconnected and that to try them separately could subject the plaintiff

to contrary verdicts.

27. In light of the forgoing this Court should conclude that it has not been shown by defendants that the malpractice defendants have been improperly joined in this action with the products liability defendants and should conclude further that both claims should be tried together in one action.

28. As the malpractice defendants have not been improperly joined, there lacks diversity of citizenship in this action and thus this Court does not have subject matter jurisdiction and the action should be remanded.

Unanimity

29. "It is ... well settled in this jurisdiction that all defendants must join a removal petition or else the petition is defective and the case must be remanded." *Bill Wolf Petroleum Corp. v. Village of Port Washington North* 489 F.Supp.2d 203, 207 (E.D.N.Y., 2007.) Thus as the malpractice defendants, served September and October of this year (Exhibit H) have not joined in the removal, it is procedurally defective due to a lack of unanimity.

Conclusion

30. In view of the foregoing, it is respectfully requested that Plaintiffs' motion be granted and that the Court order a remand of this action to the New York County Supreme Court of the State of New York, and grant such other and further relief as to this Court seems just and proper.

Dated: Brooklyn, New York

December 26, 2007

_____/s_____
Louis J. Schepp

JUDGE HOLWELL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

07 CV 10591

-----X
SONIA URRIOLA,

Plaintiff,

-against-

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC CORPORATION,
MICHAEL LIOU, M.D., BETH ISRAEL MEDICAL
CENTER AND BETH ISRAEL MEDICAL CENTER
PHILIPS AMBULATORY CARE CENTER,

Defendants.
-----X

Removed from:
Supreme Court of the State of
New York
County of New York
Index No.: 07/114306

State Case No. 1214306
Civil Action No: _____

**NOTICE OF REMOVAL
AND COPIES OF ALL
PROCESS AND
PLEADINGS**

**U.S.D.C. S.D. N.Y.
CASHIERS**

**TO: THE CLERK AND JUDGES OF THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NOTICE OF REMOVAL OF CIVIL ACTION

Defendants Guidant Corporation ("Guidant"), Guidant Sales Corporation ("GSC"), and Boston Scientific Corporation ("Boston Scientific"), pursuant to 28 U.S.C. §§ 1441 and 1446, file this Notice of Removal ("Notice") of this action from the Supreme Court of the State of New York, County of New York, to the United States District Court for the Southern District of New York. The grounds for removal are as follows:

INTRODUCTION

1. On October 24, 2007, Plaintiff brought this action against Defendants Guidant; GSC; Boston Scientific; Michael Liou, M.D.; Beth Israel Medical Center; and Beth Israel Medical Center Philips Ambulatory Care Center. The action was filed in New York Supreme Court, New York County, and bears Index No. 114306/07.

2. Plaintiff alleges serious injuries as the result of the implantation of a cardiac medical device allegedly manufactured and/or sold by Guidant, GSC, and Boston Scientific (collectively "Guidant Defendants"), and implanted by Dr. Liou and the Beth Israel Medical Center entities (collectively "Healthcare Defendants"). *See generally* Complaint (attached as Exhibit 1).

3. Plaintiff alleges that the Guidant Defendants manufactured, designed, marketed and sold Plaintiff's cardiac medical device. *See generally* Complaint.

4. Plaintiff alleges that the Healthcare Defendants were medical providers that negligently treated Plaintiff before, during, and subsequent to the implantation of her cardiac medical device. *Id.*

5. The Court has original jurisdiction over this action under 28 U.S.C. § 1332, and this action is removable under 28 U.S.C. § 1441(b), in that, excluding the fraudulently and/or misjoined defendants, it is a civil action between citizens of different states and the amount in controversy exceeds the sum of \$75,000, exclusive of interest and costs. The presence of in-state and non-diverse defendants is not a bar to removal because they have been improperly joined in this case to defeat diversity.

6. Pursuant to 28 U.S.C. § 1446(a), copies of all process, pleadings, orders and other papers or exhibits served upon or otherwise provided to Defendants are attached as Exhibit 2.

DIVERSITY OF CITIZENSHIP EXISTS

7. Plaintiff Sophia Urriola is now and was at the commencement of this action a citizen of the State of New York.

8. Guidant is now and was at the commencement of this action an Indiana corporation with its principal place of business in Minnesota. Thus, Guidant is a citizen of both Indiana and Minnesota.

9. Boston Scientific Corporation is now and was at the commencement of this action a Delaware corporation with its principal place of business in Massachusetts. Thus, Boston Scientific Corporation is a citizen of both Delaware and Massachusetts.

10. GSC is now and was at the commencement of this action a Minnesota corporation with its principal place of business in Minnesota. Thus, GSC is a citizen of Minnesota.

11. The Healthcare Defendants are now and were at the commencement of this action citizens of the State of New York. As set forth below, however, their citizenship should be disregarded for purposes of determining whether diversity jurisdiction exists or whether 28 U.S.C. § 1441(b) applies.

THE AMOUNT IN CONTROVERSY EXCEEDS \$75,000

12. Where, as here, the jurisdictional amount is not specifically alleged, it can nevertheless be determined when it is “facially apparent” from the complaint itself. *See Burr v. Toyota Motor Credit Co.*, 478 F. Supp. 2d 432, 439 (S.D.N.Y. 2006) (finding it evident “from the face of the Complaint that Plaintiffs’ claim will exceed seventy-five thousand dollars.”); *Williams v. Best Buy Co.*, 269 F.3d 1316, 1319 (11th Cir. 2001) (holding that the district court may consider whether jurisdictional amount is “facially apparent” from the complaint). A court may also consider the removal notice and post-removal evidence concerning the amount in controversy. *See id.*

13. In this case, it is “facially apparent” that the amount in controversy exceeds \$75,000. Indeed, Plaintiff alleges that she suffered “from physical and emotional injuries and severely diminished quality of life and life expectancy and was caused to and will be caused to expend sums of money for medical care and monitoring.” See Complaint ¶ 42. More specifically, Plaintiff alleges to have suffered “a significant and life threatening [fungal] infection which required the removal of her implantable cardiac defibrillator as well as extensive hospitalization thereafter, and she became and still is, and for a long time to come, will be sick, sore, lame, bruised, injured, wounded and disabled in the various parts of her head, body, and Plaintiff otherwise sustains psychological injuries, and upon information and belief all the aforementioned injuries are permanent. By reason of the foregoing the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals, surgical intervention, rehabilitation services and medical supplies in an attempt to cure herself of her injuries, and she has been prevented from performing her usual duties and will be so prevented for a long time to come.” Complaint at ¶ 48.

14. These alleged injuries are at least as serious as others that have been found to satisfy the amount in controversy. See *Burr*, 478 F. Supp. 2d at 439 (holding that plaintiff who suffered “serious and severe permanent personal injuries” as a result of a motor vehicle accident satisfied the amount in controversy); *Gebbia v. Wal-Mart Stores*, 233 F.3d 880, 888 (5th Cir. 2000) (alleged damages in a slip and fall case for “medical expenses, physical pain and suffering, mental anguish and suffering, loss of enjoyment of life, loss of wages and earning capacity, and permanent disability and disfigurement” met the jurisdictional amount); *Lockett v. Delta Airlines, Inc.*, 171 F.3d 295, 298 (5th Cir. 1999) (alleged damages to property, travel expenses, emergency ambulance trip, six-day hospitalization, pain and suffering, humiliation, and an inability to do housework met jurisdictional amount); *In re Fen-Phen Cases*, Nos. 8:01-CV-1587-

T-30-MAP et al., slip op. at 5 (M.D. Fla. Dec. 4, 2001) (similar allegations against pharmaceutical manufacturer met jurisdictional amount) (Ex. 3). *See Haran v. Medtronic, Inc.*, No. 97-C-6459, 1998 WL 575278, at *3 (N.D. Ill., Sept. 3, 1998).¹

15. Additionally, there are over 2000 cases that have been filed in or removed to federal court against one or more of the Guidant Defendants nationwide in which plaintiffs, like the Plaintiff identified in this lawsuit, allege that they are seeking compensatory damages for various personal injuries allegedly caused by an implantable cardiac medical device. More than 1990 of these cases have been consolidated in *In re: Guidant Corp. Implantable Defibrillators*, MDL No. 05-1708, which is pending before the Honorable Donovan W. Frank in the United States District Court for the District of Minnesota. Defendants' good-faith belief and estimate, based on the experience of their counsel in similar matters, is that the amount in controversy in this case exceeds \$75,000, exclusive of interest and costs. *See Rubel v. Pfizer Inc.*, 361 F. 3d 1016, 1020 (7th Cir. 2004); *Fields*, 2006 U.S. Dist. LEXIS 47948 at *3-6.

REMOVAL IS OTHERWISE PROPER

16. Plaintiff commenced this action on October 24, 2007. Plaintiff also served Boston Scientific and GSC on October 25, 2007. Thus, this removal is timely pursuant to 28 U.S.C. 1446(b).

17. Venue exists in the Southern District of New York because the Supreme Court of the State of New York, County of New York, is within this District.

18. Written notice of the filing of the Notice of Removal will be promptly served on all counsel, and a copy will be promptly filed with the Clerk of the Supreme Court of the State of New

¹ In *Haran*, the plaintiff's complaint alleged damages including physical and emotional harm and economic loss as a result of the implantation of an allegedly defective pacemaker. *See id.* The court found to a reasonable probability that the "gravity of these alleged injuries support an inference that the amount in controversy here is greater than \$75,000." *Id.* at *3.

York, County of New York, pursuant to 28 U.S.C. § 1446(d). A copy of the Notice of Filing of Notice of Removal to Federal Court is attached hereto as Exhibit 4.

19. As stated above and set forth more fully below, the Healthcare Defendants are fraudulently and/or improperly joined. Thus, their consent to this removal is unnecessary. *See In re Rezulin*, 133 F. Supp. 2d 272, 295 (S.D.N.Y. 2001) (“the failure of an improperly joined party to participate in the petition will not defeat removal”).

**THE HEALTHCARE DEFENDANTS ARE IMPROPERLY JOINED
TOGETHER IN THIS ACTION**

20. Plaintiff in this case has improperly joined the medical negligence claims asserted against the Healthcare Defendants with the product liability claims asserted against the Guidant Defendants.

21. Rule 20(a), Fed. R. Civ. P., limits permissive joinder of parties to “claims arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all these persons will arise in the action.”²

22. Here, Plaintiff’s medical-negligence claims against the Healthcare Defendants do not arise out of the same transaction or occurrence or series of transactions or occurrences as the product liability claims against the Guidant Defendants. The claims are factually and legally distinct.

23. In fact, in her Complaint Plaintiff separates her claims against the Guidant Defendants from her claims against the Healthcare Defendants. Plaintiff states only medical malpractice and lack of informed consent claims against the Healthcare Defendants (Counts 8 and 9). The remaining claims – design defect, manufacture defect, negligence, breach of express

² New York Rule of Civil Procedure 20(a) is identical to Federal Rule 20(a).

warranty, breach of implied warranty, fraudulent misrepresentation, and fraudulent concealment – are asserted against only the Guidant Defendants (Counts 1 through 7).

24. The crux of Plaintiff's claims against the Healthcare Defendants arise from their allegedly negligent care and treatment of Plaintiff. Contract at ¶ 118. In contrast, Plaintiff's claims against the Guidant Defendants involve the design, testing, manufacturing, and sale of Plaintiff's cardiac medical device.

25. Moreover, the evidence in support of these distinct claims will necessarily be different. On the one hand, Plaintiff will need to establish that the Guidant Defendants manufactured, designed and/or sold a defective cardiac medical device. On the other hand, Plaintiff will need to establish that the Healthcare Defendants "departed from accepted practices" in their care and treatment of the plaintiff. In fact, it appears that the claims will not require any of the same proof. *See, e.g., Greene v. Wyeth*, 344 F. Supp. 2d 674, 683 (D. Nev. 2004) (severing medical negligence claims against non-diverse doctor who prescribed diet medications from the product liability claims against the manufacturer because the claims were improperly joined).

26. Plaintiff's claims arising out of the Healthcare Defendants' care and treatment of the plaintiff do not arise out of the same "transaction or occurrence" as his claims against the Guidant Defendants. Thus, those claims should be severed. *See, e.g., In re Rezulin*, 168 F. Supp. 2d 136, 144-148 (S.D.N.Y. 2001) (finding that claim against home healthcare provider was misjoined with claims against drug manufacturer).

27. Courts may sever improperly joined parties when their claims do not arise out of the same transaction or occurrence, or the claims will not involve questions of law or fact common to all parties. Federal Rule of Civil Procedure 21 provides that "[p]arties may be

dropped or added by order of the court...at any stage of the action and on such terms that are just.”³

28. Indeed, in this very litigation, the MDL Court recently, under similar circumstances, severed medical negligence claims against a healthcare provider from the product liability claims against Guidant in order to retain jurisdiction of the plaintiff’s claims against Guidant. *See Brown v. Guidant Corp., et. al.*, MDL No. 1708 (D. Minn. August 30, 2007) (Frank, J.) (Order denying Motion to Remand and Severing claims against healthcare providers) (attached as Exhibit 5). Specifically, in *Brown*, the plaintiff, like the plaintiff here, joined medical negligence claims against Plaintiff’s non-diverse implanting physician with product liability claims against diverse defendant Guidant. *Id.* at p. 3. Guidant removed the action from California state court on the basis that the medical negligence claims were misjoined with the product liability claims. *Id.* Plaintiff moved for remand arguing that the surgery and implantation of the device shared “common questions of law and/or fact” with the product liability claims against Guidant. *Id.* In denying the motion to remand and severing the claims against the non-diverse physician, Judge Frank stated:

[Plaintiff’s] claim against Dr. Housman is medical negligence, which would require evidence on [Plaintiff’s] care, treatment, and services provided by Dr. Housman. Brown’s claims against either Guidant or EVT are general negligence or product liability claims based on alleged manufacturing and design defects, alleged failure to properly warn, and alleged misrepresentation of the health risks associated with certain medical devices. These claims would require evidence on the development, manufacture, and testing of [Plaintiff’s device] along with evidence of Guidant and EVT’s knowledge, warnings, and representations regarding defective [devices.] The joinder of the malpractice claims against Dr. Housman with the other general negligence and product liability claims was inappropriate because the claims do not both involve common questions of law or fact and assert joint, several, or alternative liability “arising out of the same transaction or occurrence, or series of transactions or occurrences.”

³ New York Rule of Civil Procedure 21 is identical to its federal counterpart.

Id. at 5-6. The facts of this case are indistinguishable.

29. Likewise, in *Alexander v. Guidant Corp.*, Case No. 05-1708, (D. Minn. June 4, 2007) (attached hereto as Exhibit 6), the MDL Court found: “[t]he joinder of the malpractice claim against [the healthcare provider] with the other product liability claims was inappropriate because the claims do not both involve common questions of law or fact and assert joint, several or alternative liability arising out of the same transaction, occurrence, or series of transactions or occurrences. Any liability that may be found against either [Guidant or the healthcare facility] would not be a basis for liability as to the other.” *Id.* at 12.

30. Moreover, in a similar case pending against Guidant, the United States District Court for the Southern District of Texas also found that joinder of non-diverse medical negligence defendants was improper. *Hardin v. Guidant Corp., et al.*, Case No. G-05-430 (S.D. Tex. February 1, 2006) (attached hereto as Exhibit 7). In that case, the plaintiff, like the Plaintiff here, filed in the same complaint causes of action against healthcare providers alleging medical negligence and causes of action against Guidant alleging product liability. *Id.* The court found that the joinder of the medical negligence claims against the non-diverse healthcare providers was improper. *Id.* The court ordered that the medical negligence claims be severed and remanded, and it retained jurisdiction over the product liability claims against Guidant. *Id.*

31. The principals stated in the cases cited above are equally applicable here where Plaintiff asserts that Guidant is liable for allegedly manufacturing, designing, and selling a defective product, and in the same complaint asserts that the Healthcare Defendants breached the applicable standard of care in their treatment of Plaintiff. These two claims will require different

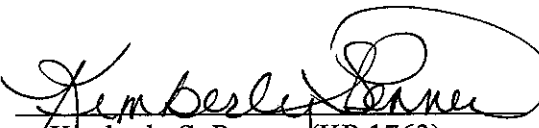
evidence and do not arise out of the same occurrence, transaction or series of occurrences or transactions.

32. The Guidant Defendants, therefore, respectfully request that this Court sever the medical negligence claims against the Healthcare Defendants from the product liability claims against the Guidant Defendants and retain jurisdiction over the product liability claims against the Guidant Defendants.

Dated: November 26, 2007

Respectfully submitted,

By:



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Attorneys for Defendants
Guidant Corporation,
Guidant Sales Corporation and
Boston Scientific Corporation

EXHIBIT 1

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

Plaintiffs,

VERIFIED COMPLAINT

-against-

Index No.: 114306 /07

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC
CORPORATION, MICHAEL LIU, M.D., BETH
ISRAEL MEDICAL CENTER AND BETH ISRAEL
MEDICAL CENTER PHILIPS AMBULATORY CARE
CENTER,

Defendants,
-----X

Plaintiffs, by and through their attorneys, Bonina & Bonina, P.C., complaining of the
defendants herein, as and for their Verified Complaint in the above entitled action, respectfully show
to this Court and allege upon information and belief as follows:

**AS AND FOR A FIRST CAUSE OF ACTION ON BEHALF OF PLAINTIFF
SONIA URRIOLA TO RECOVER MONETARY DAMAGES FROM THE
DEFENDANTS UNDER A THEORY OF DEFECT IN DESIGN**

FIRST:

That prior to service of this Summons & Complaint and on the 24th day of October 2007,
plaintiffs have purchased Index No. _____/07 from the Supreme Court of the State of
New York, County of New York, in accordance with the requirements of the CPLR.

SECOND:

That this action falls within one or more exceptions set forth in CPLR §1602.

THIRD:

Plaintiffs demand a trial by jury.

FOURTH:

That all times mentioned herein, plaintiff, Sonia Urriola, is, was, and has been a resident of the County of New York, City and State of New York.

FIFTH:

That at all times mentioned herein, Defendant Guidant, (hereinafter Guidant) is a foreign corporation with its principal place of business in a state other than New York.

SIXTH:

Defendant Guidant manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model number H179.

SEVENTH:

That at all times herein mentioned, the Defendant Guidant, was and still is a foreign corporation duly authorized to do business in the State of New York.

EIGHTH:

That at all times mentioned herein, Defendant Guidant, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

NINTH:

That at all times mentioned herein, Defendant Guidant Sales Corporation, (hereinafter Guidant Sales) is a foreign corporation with its principal place of business in a state other than New York.

TENTH:

Defendant Guidant Sales manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain implantable Cardiac Resynchronization Therapy - Defibrillators (CRT-D) and including the Contak Renewal 3HE Model number H179.

ELEVENTH:

That at all times herein mentioned, the Defendant Guidant Sales, was and still is a foreign corporation duly authorized to do business in the State of New York.

TWELFTH:

That at all times mentioned herein, Defendant Guidant Sales, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

THIRTEENTH:

That at all times mentioned herein, defendant Boston Scientific Corporation (hereinafter Boston) is a corporation incorporated pursuant to the laws of the State of Delaware and has its principal place of business in Massachusetts.

FOURTEENTH:

Defendant Boston manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 4HE Model number H179.

FIFTEENTH:

That at all times mentioned herein, the Defendant Boston, was and still is a domestic corporation duly organized and existing under and by virtue of the laws of the State of New York.

SIXTEENTH:

That at all times mentioned herein, the Defendant Boston, was and still is a foreign corporation duly authorized to do business in the State of New York.

SEVENTEENTH:

That at all times mentioned herein, Defendant Boston, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

EIGHTEENTH:

That at all times mentioned herein Defendant Boston, is, was and has been a limited partnership or limited liability company duly organized under and existing by virtue of the laws of the State of New York.

NINETEENTH:

That upon information and belief the defendant Boston has acquired or merged with the defendant Guidant and/or defendant Guidant Sales and is a successor in interest to all claims articulated herein and stated against defendants Guidant and Guidant Sales.

TWENTIETH:

At all times, defendants were engaged in the business of manufacturing, selling, distributing, promoting, designing and testing Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179.

TWENTY FIRST:

Each defendant placed the Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179, into the stream of commerce and derived substantial benefits from this product which was sold for profit in the State of New York by the

defendants, their agents, servants, associates, subsidiaries, partners and/or employees.

TWENTY SECOND:

At all times hereinafter mentioned all of the above named defendants regularly did and/or transacted and/or solicited business in the State of New York or were engaged in other persistent courses of conduct or derived substantial revenue from goods used or consumed or services rendered in the State of New York.

TWENTY THIRD:

That at all times mentioned herein the defendants expected or should have reasonably expected its acts to have consequences within the State of New York, and derived and continues to derive substantial revenue from Interstate and International Commerce.

TWENTY FOURTH:

That at all times mentioned herein, defendants held themselves out to the general public, and more particularly to the plaintiff herein, as duly qualified and/or capable of manufacturing designing, testing, distributing, promoting and/or selling safe and proper implantable medical devices, including but not limited to the Contak Renewal 3HE Model H179 within the State of New York.

TWENTY FIFTH:

That at all times mentioned herein, the defendants for consideration held themselves out as distributing, manufacturing, designing and selling proper, adequate and safe implantable medical devices, namely the Contak Renewal 3HE Model H179 to members of the general public and more particularly plaintiff herein, and further held themselves out to such individuals as having the necessary skills, expertise, training, and/or personnel, equipment and supplies to perform the same up to the standards of such care prevalent within the Local, State, and National Community.

TWENTY SIXTH:

At all times mentioned herein, defendants themselves, or by use of others did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, advertise, warn, and otherwise distribute in interstate commerce the Contak Renewal 3HE Model H179.

TWENTY SEVENTH:

The Contak Renewal 3HE Model H179 was widely advertised by the defendants in the State of New York and throughout the United States for use by persons with irregular cardiac rhythms.

TWENTY EIGHTH:

Upon information and belief the defendant manufactured an implantable device named the Contak Renewal 3HE Model H179, which was designed, manufactured, marketed, tested, distributed and sold for profit in the State of New York by one or more of the defendants herein.

TWENTY NINTH:

At all times relevant herein, the defendants were engaged in the business of manufacturing, marketing, promoting, selling, distributing and placing in the stream of commerce an implantable cardiac defibrillator device known as the Contak Renewal 3HE Model H179. Upon information and belief each defendant engaged in advertising and promotional activity which indicated its product was efficacious and safe to use and, that based upon the defendants promotional activity with respect to the aforesaid product, said product was implanted into the plaintiff's body based upon the belief that the same was safe to use and was unlikely to subject the plaintiff to any serious danger or injury as a result of the use of the product.

THIRTIETH:

That the aforesaid Product was and is sold to hospitals and physicians for implantation into patients who are at risk for having life threatening arrhythmia's as a result of electro physiological changes in the hearts rhythms resulting in a change in heart rhythm, which are life threatening if the patient does not receive an electrical shock from an appropriate device.

THIRTY FIRST:

Defendant's aforesaid Product contains wires, called leads, inserted through blood vessels and attached to the heart to detect irregularity in the hearts rhythm and to deliver an electrical shock to prevent or terminate an arrhythmia.

THIRTY SECOND:

In on or about November 4, 2004, the plaintiff Sonia Urriola underwent surgery for the implantation of a Guidant Contak Renewal 3HE Model H179 cardiac defibrillator with serial number 504858.

THIRTY THIRD:

Upon information and belief, the Guidant Contak Renewal 3HE Model H179 was manufactured, promoted, and marketed by the defendants, and/or each of them, as a safe medical device that would be beneficial for cardiac patients at risk for arrhythmia.

THIRTY FOURTH:

Upon information and belief, defendants and/or each of them were in control of the design, manufacture testing, labeling, warning, product information, packaging, promoting, assembly, manufacture, marketing, distribution and/or sales the aforementioned implantable cardiac defibrillator.

THIRTY FIFTH:

Defendants made filings with the United States Food and Drug Administration (hereinafter referred to as FDA) in conjunction with the approval process for the Contak Renewal 3HE Model H179.

THIRTY SIXTH:

Defendants promoted the Guidant Contak Renewal 3HE Model 179 as a therapy to reduce the risk of hospitalization or death and as a device that could relieve symptoms associated with heart failure, including shortness of breath and fatigue.

THIRTY SEVENTH:

That said Contak Renewal 3HE Model H179 came equipped with certain standard equipment, including, among other things, certain wires and/or leads which were improperly and/or inadequately insulated.

THIRTY EIGHTH:

That said Contak Renewal 3HE Model H179, came equipped with certain standard equipment, including, among other things, certain and/or switches which were improperly and/or inadequately manufactured and were prone to stitching.

THIRTY NINTH:

That the Contak Renewal 3HE Model 179 came equipped with certain standard equipment including among other things, low voltage capacitors which were subject to degradation.

FORTIETH:

That said wires and/or leads and/or seals and/or low voltage capacitors were an integral and inherent part of the safety equipment of the above referenced Contak Renewal 3HE Model H179, the

purpose of which was to provide proper protection to the ordinary and foreseeable users and consumers of said device.

FORTY FIRST:

Sonia Urriola had a Guidant Contak Renewal 3HE Model 179 Serial number 504858 implanted on or about November 4, 2004 and it remained implanted until on or about June 29, 2007.

FORTY SECOND:

Subsequent to having the Guidant Contak Renewal 4HE Model 179 implanted plaintiff, Sonia Urriola, suffered from physical and emotional injuries and severely diminished quality of life and life expectancy and was caused to and will be caused to expend sums of money for medical care and monitoring.

FORTY THIRD:

The product warnings in effect between October 2005 and June 2007 were both substantially and wholly inadequate to alert prescribing physicians and consumer patients of the risk of injury and infection associated with the Guidant Contak Renewal 3HE Model H179 which were then known to the defendants.

FORTY FOURTH:

Defendants had a duty to exercise reasonable care in the design manufacture, testing, clinical trials, compiling of product information, submission of product information to FDA, pre- and post-marketing testing, sale, marketing and/or distribution of Guidant Contak Renewal 3HE Model H179 into the stream of commerce, including a duty to insure the product did not cause users to suffer from unreasonable and dangerous side effects and injuries as a result of having the product implanted.

FORTY FIFTH:

Defendants failed to exercise ordinary care in the manufacturing, selling, testing, quality assurance, quality control and/or distribution of Guidant Contak Renewal 3HE Model 179 into interstate commerce in that defendants knew or reasonably should have known that the product created an increased risk for unreasonable dangerous side effects some of which could only be alleviated by invasive and/or surgical procedures, and some of which can be fatal.

FORTY SIXTH:

Defendants and/or each of them, and/or their agents, servants, subsidiaries, partners, associates and employees, acted negligently, carelessly and recklessly, and in willful and wanton disregard for the health, life and safety of their consumers and the public, with respect to their distribution, manufacture, testing, marketing, advertising, and sale of the Contak Renewal 3HE Model H179 in the following ways:

- a. Negligently, carelessly and recklessly manufactured, constructed, engineered, inspected, marketed, tested, and sold implantable cardiac devices that included a seal that leaked allowing moisture to damage electrical components;
- b. Negligently, carelessly and recklessly designed, constructed, engineered, inspected, marketed, tested and sold implantable cardiac devices that included a seal that stuck allowing moisture to damage electrical components;
- c. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant injury;
- d. Failed to adequately and timely advise consumers and healthcare providers of the

dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant life threatening infections;

- e. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators, including the Contak Renewal 3HE Model 179, that had leads and/or wires that were not properly insulated;
- f. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators that had inadequate insulation material on the leads and/or the wires causing these parts of the Contak Renewal 3HE Model H179 to have an increased risk of degradation;
- g. Manufactured, constructed, engineered, inspected, distributed, marketed, tested and sold implantable cardiac defibrillators which were a significant risk of injury to consumers, and in particular to the plaintiff herein;
- h. Knew or reasonably should have known of the potential serious side effects, including but not limited to infection and surgical intervention, and failed to properly investigate and research these issues in clinical trials;
- i. Knew or reasonably of should have known of the potential serious side effects including but not limited to infection and the need for surgical intervention and failed to properly investigate and perform/post sale and adequate post marketing follow up studies;
- j. Failed and omitted to provide adequate information to medical professionals regarding the risks associated with the implantation of Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179;

- k. Failed and/or omitted to inform medical professionals of the significant risk of infection as a result of degradation of the leads/wires;
- l. Manufactured, constructed, distributed, marketed, inspected, tested, and sold a implantable cardiac defibrillator which was unsafe and unfit for its reasonable, ordinary and foreseeable uses;
- m. Caused, allowed and permitted a dangerous defective and unsuitable product to be marketed to the medical profession for use in patients who were medically dependent upon a properly working defibrillator;
- n. Failed to adequately warn members of the medical profession of the risks and dangers inherent in the insertion and use of the Contak Renewal 3HE implantable cardiac defibrillator Model 179;
- o. Failed and/or omitted to properly test the device to determine its effectiveness, and the effectiveness of the insulation on the leads/wires;
- p. Failed and/or omitted to properly instruct members of the medical profession as to the proper manner of testing the device, as well as the proper methods of monitoring patients for defects in the device;
- q. Failed and omitted to properly design, manufacture, assemble, sell, distribute and promote a product that members of the public, including the plaintiff herein, relied upon to sustain life;
- r. Failed and omitted to exercise reasonable and ordinary care and due diligence in ascertaining the defective condition and improper design and manufacturing defects in the Contak Renewal 3E Model H179 implantable cardiac defibrillator;

- s. Failed and omitted to protect the public interest and more particularly that of the plaintiff herein;
- t. Manufactured, distributed, engineered, delivered, sold and marketed an implantable cardiac defibrillator which was inherently dangerous to the life and health of the public, its intended and foreseeable users and more particularly to the plaintiff herein;
- u. Failed and omitted to adopt and enforce proper inspection and testing techniques procedures and protocols on each and every cardiac defibrillator designed, manufactured, constructed, engineered, assembled, sold and distributed including the Contak Renewal 3HE Model H179;
- v. Failed and omitted to properly and adequately notify members of the medical profession regarding the defects present in the Contak Renewal 3HE Model H179 cardiac defibrillator; and
- w. Failed and omitted to institute proper, adequate and timely recall procedures.

FORTY SEVENTH:

As a result of defendants' defectively designed Cardiac Resynchronization Therapy - Defibrillators (CRT-D), plaintiff required surgery and extensive rehabilitation and suffered serious infection as a result of the Contak Renewal 3HE Model H179.

FORTY EIGHTH:

As a result of the above referenced conduct of the defendants and/or their subsidiaries, successors and interests, divisions, agents, servants, associates, partners and/or employees, the plaintiff Sonia Urriola was caused to suffer a significant and life threatening infection which required the removal of her implantable cardiac defibrillator as well as extensive hospitalization thereafter, and

she became and still is, and for a long time to come, will be sick, sore, lame, bruised, injured, wounded, and disabled in the various parts of her head, body, and plaintiff otherwise sustains psychological injuries, and upon information and belief all the aforementioned injuries are permanent. By reason of the foregoing the plaintiff, Sonia Urriola was obliged to and did necessarily employ hospital aid, medical aid, medicinals, surgical intervention, rehabilitation services and medical supplies in an attempt to cure herself of her injuries, and she has been prevented from performing her usual duties and will be so prevented for a long time to come.

FORTY NINTH:

That the plaintiff is not seeking to recover any damages for which plaintiff has been reimbursed by insurance or other applicable coverage. Plaintiff is only seeking to recover those damages not recoverable through insurance and/or other applicable coverage under the facts and circumstances in this action.

FIFTIETH:

That as a result of the aforementioned, the plaintiff Sonia Urriola, has been damaged in an amount exceeding all jurisdictional limits of the lower Courts.

**AS AND FOR A SECOND CAUSE OF ACTION ON BEHALF OF
THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY OF
STRICT PRODUCTS LIABILITY FOR A DEFECT IN MANUFACTURE**

FIFTY FIRST:

That the Plaintiff, SONIA URRIOLA, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "FIFTIETH", with the same force and effect as though said allegations were here and fully set forth at length.

FIFTY SECOND:

That reasonable reliance upon the proper function of said Contak Renewal 3HE Model H179 device, the plaintiff, Sonia Urriola had said Contak Renewal 3HE Model H179 implanted on or about November 4, 2004.

FIFTY THIRD:

That, while the plaintiff had said device implanted as aforesaid, said device caused serious and severe injuries to the Plaintiff herein, including but not limited to massive fungal infection.

FIFTY FOURTH:

That, upon information and belief, the happening of the occurrence as aforesaid was the result of defects in manufacture, which caused the Plaintiff to suffer and sustain serious and severe injuries.

FIFTY FIFTH:

That, at all times mention herein, the Defendants knew and/or reasonably should have known the intended use to which said Contak Renewal 3HE Model H179 and its appurtenances would be put, and that the general public, and more particularly the Plaintiff herein, would be involved in said uses.

FIFTY SIXTH:

That, at all times mentioned herein, the Defendants and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, failed to exercise the proper and reasonable degree of care in the manufacturing, assembling, sterilizing, engineering, and insertion of the Contak Renewal 3HE Model H179, causing said Contak Renewal 3HE Model H179 to be dangerously defective, and not reasonably safe for its ordinary, intended and foreseeable purposes.

FIFTY SEVENTH:

Defendants and/or each of them, and/or their agents, servants, partners, associates and employees, acted negligently, carelessly and recklessly, and in willful and wanton disregard for the health, life and safety of their consumers and the public, with respect to their distribution, manufacture, testing, marketing, advertising, and sale of the Contak Renewal 3HE Model H179 in the following ways:

- a. Negligently, carelessly and recklessly manufactured, constructed, engineered, inspected, marketed, tested, and sold implantable cardiac devices that included a seal that leaked allowing moisture to damage electrical components;
- b. Negligently, carelessly and recklessly designed, constructed, engineered, inspected, marketed, tested and sold implantable cardiac devices that included a seal that stuck allowing moisture to damage electrical components;
- c. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant injury;
- d. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant life threatening infections;
- e. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators, including the Contak Renewal 3HE Model 179, that had leads and/or wires that were not properly insulated;
- f. Manufactured, constructed, engineered, inspected, marketed, tested and sold

implantable cardiac defibrillators that had inadequate insulation material on the leads and/or the wires causing these parts of the Contak Renewal 3HE Model H179 to have an increased risk of degradation;

- g. Manufactured, constructed, engineered, inspected, distributed, marketed, tested and sold implantable cardiac defibrillators which were a significant risk of injury to consumers, and in particular to the plaintiff herein;
- h. Knew or reasonably should have known of the potential serious side effects, including but not limited to infection and surgical intervention, and failed to properly investigate and research these issues in clinical trials;
- i. Knew or reasonably should have known of the potential serious side effects including but not limited to infection and the need for surgical intervention and failed to properly investigate and perform/post sale and adequate post marketing follow up studies;
- j. Failed and omitted to provide adequate information to medical professionals regarding the risks associated with the implantation of Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179;
- k. Failed and/or omitted to inform medical professionals of the significant risk of infection as a result of degradation of the leads/wires;
- l. Manufactured, constructed, distributed, marketed, inspected, tested, and sold a implantable cardiac defibrillator which was unsafe and unfit for its reasonable, ordinary and foreseeable uses;
- m. Caused, allowed and permitted a dangerous defective and unsuitable product to be

marketed to the medical profession for use in patients who were medically dependent upon a properly working defibrillator;

- n. Failed to adequately warn members of the medical profession of the risks and dangers inherent in the insertion and use of the Contak Renewal 3HE implantable cardiac defibrillator Model 179;
- o. Failed and/or omitted to properly test the device to determine its effectiveness, and the effectiveness of the insulation on the leads/wires;
- p. Failed and/or omitted to properly instruct members of the medical profession as to the proper manner of testing the device, as well as the proper methods of monitoring patients for defects in the device;
- q. Failed and omitted to properly design, manufacture, assemble, sell, distribute and promote a product that members of the public, including the plaintiff herein, relied upon to sustain life;
- r. Failed and omitted to exercise reasonable and ordinary care and due diligence in ascertaining the defective condition and improper design and manufacturing defects in the Contak Renewal 3E Model H179 implantable cardiac defibrillator;
- s. Failed and omitted to protect the public interest and more particularly that of the plaintiff herein;
- t. Manufactured, distributed, engineered, delivered, sold and marketed an implantable cardiac defibrillator which was inherently dangerous to the life and health of the public, its intended and foreseeable users and more particularly to the plaintiff herein;
- u. Failed and omitted to adopt and enforce proper inspection and testing techniques,

procedures and protocols on each and every cardiac defibrillator designed, manufactured, constructed, engineered, assembled, sold and distributed including the Contak Renewal 3HE Model H179;

- v. Failed and omitted to properly and adequately notify members of the medical profession regarding the defects present in the Contak Renewal 3HE Model H179 cardiac defibrillator; and
- w. Failed and omitted to institute proper, adequately and timely recall procedures.

FIFTY EIGHTH:

That as a result of the above referenced conduct of the Defendant, and/or its subsidiaries, divisions, successors in interest, agents, servants, associates, partners, and/or employees, the Plaintiff, Sonia Urriola, was caused to suffer a massive fungal infection requiring removal of the device and surgical interventions and became, still is, and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her body and said plaintiff otherwise sustained psychological injuries, and upon information and belief said injuries are permanent, that by reason of the foregoing, the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals, and medical supplies in an attempt to cure herself of said injuries, and has been prevented from performing her usual duties and will be so prevented for a long time to come.

FIFTY NINTH:

That by reason of the foregoing, the Plaintiff, Sonia Urriola, has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A THIRD CAUSE OF ACTION ON BEHALF OF
THE PLAINTIFF, SONIA URRIOLA, BASED UPON A
THEORY OF NEGLIGENCE**

SIXTIETH:

That the Plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "FIFTY EIGHTH", with the same force and effect as though said allegations were herein fully set forth at length.

SIXTY FIRST:

That on or about June 29, 2007 as a result of the insertion of Contak Renewal 3HE Model 179, the Plaintiff, Sonia Urriola, was caused to suffer a massive fungal infection requiring removal of the device and resulting in serious and severe injuries.

SIXTY SECOND:

That the aforementioned occurrence was caused wholly and exclusively as a result of the negligence, carelessness and recklessness of Defendants, and/or Defendants' divisions, successors in interest, subsidiaries, agents, servants, associates, partners, and/or employees without any negligence or culpable conduct on the part of the Plaintiff, Sonia Urriola, contributing thereto.

SIXTY THIRD:

That Defendants, and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, actually and/or reasonably knew or should have known at the time of the design and/or manufacture of the aforesaid Contak Renewal 3HE Model H179, that said device was dangerously defective, hazardous, unsafe, dangerous, and posed certain dangers and it was unfit for its ordinary, normal and foreseeable usages by intended users and/or operators.

SIXTY FOURTH:

That, upon information and belief, the happening of the occurrence as aforesaid was the result of the negligence, carelessness and recklessness of defendants, and/or each of them which caused the Plaintiff to suffer and sustain serious and severe injuries.

SIXTY FIFTH:

That, at all times mention herein, the Defendants knew and/or reasonably should have known the intended use to which said Contak Renewal 3HE Model 179 and its appurtenances would be put, and that the general public, and more particularly the Plaintiff herein, would be involved in said uses.

SIXTY SIXTH:

That, at all times mentioned herein, the Defendants and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, failed to exercise the proper and reasonable degree of care in the manufacturing, assembling, engineering, and inserting of the Contak Renewal 3HE Model 179, causing said Contak Renewal 3HE Model 179 to be dangerously defective, and not reasonably safe for its ordinary, intended and foreseeable purposes.

SIXTY SEVENTH:

That as a result of the above referenced conduct of the Defendants, and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, the Plaintiff, Sonia Urriola, was caused to suffer injuries and became, still is, and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her head, body, fingers, limbs, extremities, and hands, and said Plaintiff otherwise sustained psychological injuries, and upon information and belief said injuries are permanent, that by reason of the foregoing, the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals and medical

supplies in an attempt to cure himself of said injuries, and has been prevented from performing his usual duties and will be so prevented for a long time to come.

SIXTY EIGHTH:

That by reason of the foregoing, the Plaintiff, Sonia Urriola, has been damaged in a sum exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A FOURTH CAUSE OF ACTION ON BEHALF
OF THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY
OF BREACH OF EXPRESS WARRANTY**

SIXTY NINTH:

That the plaintiff, Sonia Urriola repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "SIXTY EIGHTH", with the same force and effect as though said allegations were herein and fully set forth at length.

SEVENTIETH:

Defendants expressly warranted to the plaintiff that the product which they designed, developed, manufactured and sold was of a merchantable quality, fit, safe and otherwise beneficial to the plaintiff's health and well being and that it would improve the quality of plaintiff's life.

SEVENTY FIRST:

Defendants' representations formed a part of the basis of the bargain and plaintiff, Sonia Urriola relied upon said representations in deciding to have the product implanted.

SEVENTY SECOND:

That the product implanted in the plaintiff was unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to the plaintiff, Sonia Urriola and did not operate as represented.

SEVENTY THIRD:

Through the sale of the product, the defendants and/or each of them are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

SEVENTY FOURTH:

Defendants breached the express warranty of merchantability in sale of the product to Sonia Urriola and said products was not fit for its ordinary purpose as described above.

SEVENTY FIFTH:

As a direct and proximate cause of the defendants breach of their express warranties described herein, the plaintiff, Sonia Urriola suffered an injury as alleged herein above.

SEVENTY SIXTH:

That by reason of the foregoing the plaintiff, Sonia Urriola has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A FIFTH CAUSE OF ACTION ON BEHALF
OF THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY
OF BREACH OF IMPLIED WARRANTY**

SEVENTY SEVENTH:

Plaintiff repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraphs "FIRST" through "SEVENTY SIXTH" with the same force and effect as those said allegations were herein fully set forth at length.

SEVENTY EIGHTH:

Defendants, and/or each of them, are in the business of manufacturing and/or supplying and/or placing into the stream of commerce for consumers implantable cardiac devices known as the Contak Renewal 3HE Model H179.

SEVENTY NINTH:

By placing the product into the stream of commerce, said defendants impliedly warranted that the product was of merchantable quality, and was fit and safe for its intended use and was fit for the particular purpose of protecting the plaintiff, Sonia Urriola from cardiac arrhythmia.

EIGHTIETH:

That the product was placed into the stream of commerce by said defendants and was unmerchantable, was not fit and was not safe for its intended use and not fit for the particular purpose intended.

EIGHTY FIRST:

That the defects in the product manufactured and/or supplied by the defendants were present at the time that the product left the hands of the defendants.

EIGHTY SECOND:

As a result, the defendants breached implied warranties for the product because said product was defective, unmerchantable, and not fit for its intended particular purpose.

EIGHTY THIRD:

The plaintiff Sonia Urriola was a foreseeable user of the product herein, and as a direct and proximate cause of the defendants' breach of implied warranty, she sustained serious, life threatening injuries.

EIGHTY FOURTH:

That by reason of the foregoing plaintiff Sonia Urriola damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A SIXTH CAUSE OF ACTION FOR
FRAUDULENT MISREPRESENTATION**

EIGHTY FIFTH:

That the plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraph "FIRST" through "EIGHTY FOURTH" with the same force and effect as those said allegations were herein fully set forth at length.

EIGHTY SIXTH:

That the defendants fraudulently and falsely represented to the medical community and to the plaintiff herein that their product had been tested and found to be safe and effective for patients with heart disease.

EIGHTY SEVENTH:

That the representations made by the defendants were in fact false.

EIGHTY EIGHTH:

That when said representations were made by the defendants that they knew those representations to be false and/or willfully, wantonly and recklessly disregarded whether the representations were true.

EIGHTY NINTH:

That these representations were made by the defendants and/or their successors in interest and/or each of them with the intent of defrauding and deceiving the plaintiff and the public in general and the medical community in particular to recommend, dispense and purchase the product all of which evidences callous, reckless, willful and depraved indifference to the health and safety and welfare of the injured plaintiff.

NINETIETH:

At the time that the aforesaid representations were made by the defendant that the injured plaintiff was unaware of the falsity of said representations and reasonably believe them to be true.

NINETY FIRST:

In reliance upon said representations the injured plaintiff was induced to and did have the product surgically implanted and thereafter sustained injury and damages as a result of the unsafe product.

NINETY SECOND:

That as a result of the defendant malicious, reckless and/or negligent conduct, the plaintiff Sonia Urriola was caused to suffer significant injuries and became and still is and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her body and that said plaintiff sustains psychological injuries and upon information and belief said injuries are permanent. By reason of the foregoing the plaintiff, Sonia Urriola was obliged to and unnecessarily did employ hospital aid, surgical intervention, medical aid, rehabilitation services and medical supplies in an attempt to cure herself of said injuries and has been prevented from performing her usual duties and will be still prevented for a long time to come.

NINETY THIRD:

That by reason of the foregoing plaintiff, Sonia Urriola has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A SEVENTH CAUSE OF ACTION FOR
FRAUDULENT CONCEALMENT WARRANTY**

NINETY FOURTH:

That the plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraph "FIRST" through "NINETY THIRD" with the same force and effect as those said allegations were herein fully set forth at length.

NINETY FIFTH:

That at all times during the course of dealings between the defendants and the injured plaintiff the defendants misrepresented that the product was safe for its intended use.

NINETY SIXTH:

The defendants knew that the representations were false as the defendants knew that there were problems with the Contak Renewal Model H179 and/or components thereof malfunctioning prior to implantation and/or injury.

NINETY SEVENTH:

That in representations to plaintiff and by withholding defect information from the FDA, thus preventing regulation, the defendants fraudulently concealed and intentionally omitted the aforesaid material information and that the product was not safe for use and was susceptible to malfunction; that the defendants were aware of the products danger and that the product was defective and that the defect caused malfunction that rendered the device useless for a period of time with the potential to cause death and severe injury and emotional distress and that the product was manufactured and designed negligently and that the product was manufactured and designed defectively and that the product was manufactured and designed improperly.

NINETY EIGHTH:

The defendants were under a duty to disclose to injured patients and their physicians, hospitals and medical providers the defective nature of their product and/or risks and dangers associated with it.

NINETY NINTH:

That the defendants had sole access to material facts concerning the defective nature of the product and the defect and the propensity to malfunction and cause serious and dangerous side effects including infection, and hence cause damage to the injured plaintiff.

ONE HUNDREDTH:

That the defendants' concealment and omission of material facts concerning the safety of the product were made purposely, willfully, wantonly, and/or recklessly to mislead injured patients and their physicians, hospital and medical providers into reliance, continued use of this product and actions thereon and to cause them to purchase this product and/or have them implanted.

ONE HUNDRED FIRST:

That the defendants knew that the patients, and in particular the plaintiff herein, and their physician, hospitals, medical providers had no way of determining the truth behind defendants' concealment and omissions and that these included material omissions of facts surrounding the product.

ONE HUNDRED SECOND:

Injured plaintiff, Sonia Urriola, as well as her doctors, health care providers and/or hospitals reasonably relied on defendants concealment and/or misstatement of fact.

ONE HUNDRED THIRD:

As a direct and proximate result of defendants malicious, reckless and/or negligent conduct the plaintiff, Sonia Urriola, suffered significant injuries that upon information and belief are permanent, and has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A EIGHTH CAUSE OF ACTION TO
RECOVER MONETARY DAMAGES FROM THE DEFENDANTS
UNDER A THEORY OF DEPARTURE FROM ACCEPTED MEDICAL
PRACTICE ON BEHALF OF THE PLAINTIFF, SONIA URRIOLA**

ONE HUNDRED FOURTH:

That the Plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "ONE HUNDRED THIRD", with the same force and effect as though said allegations were here and fully set forth at length.

ONE HUNDRED FIFTH:

That at all times mentioned herein, the defendant MICHAEL LIOU, M.D., hereinafter referred to as "LIOU", maintained offices for the practice of medicine within the County of New York, City and State of New York.

ONE HUNDRED SIXTH:

That at all times mentioned herein, the defendant "LIOU" held himself out to the general public and more particularly to the plaintiff herein as a duly qualified and/or licensed physician and/or surgeon capable of practicing medicine and/or surgery within the State of New York.

ONE HUNDRED SEVENTH:

That at all times mentioned herein the defendant "LIOU", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services,

radiology services, laboratory services, pharmacy services, diagnostic and treatment services, surgical services including pre operative and post operative services, anesthesia services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein, and further held himself out to such individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED EIGHTH:

At all times mentioned herein, the defendant BETH ISRAEL MEDICAL CENTER, hereinafter referred to as "BIMC" was and still is a corporation, duly existing pursuant to the laws of the State of New York, and doing business within the County of New York, City and State of New York.

ONE HUNDRED NINTH:

That at all times mentioned herein, the defendant "BIMC" owned, operated, supervised, maintained, and/or controlled certain premises within the County of New York, City and State of New York, for the care of sick and ailing persons, and for other individuals requiring medical care and attention, including the plaintiff herein.

ONE HUNDRED TENTH:

That at all times mentioned herein, the defendant "BIMC", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services, radiology services, laboratory services, pharmacy services, diagnostic and treatment services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein and further held itself out to such

individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED ELEVENTH:

At all times mentioned herein, the defendant BETH ISRAEL MEDICAL CENTER PHILLIPS AMBULATORY CARE CENTER, hereinafter referred to as "BIMC-PHILLIPS" was and still is a corporation, duly existing pursuant to the laws of the State of New York, and doing business within the County of New York, City and State of New York.

ONE HUNDRED TWELFTH:

That at all times mentioned herein, the defendant "BIMC-PHILLIPS" owned, operated, supervised, maintained, and/or controlled certain premises within the County of New York, City and State of New York, for the care of sick and ailing persons, and for other individuals requiring medical care and attention, including the plaintiff herein.

ONE HUNDRED THIRTEENTH:

That at all times mentioned herein, the defendant "BIMC-PHILLIPS", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services, radiology services, laboratory services, pharmacy services, diagnostic and treatment services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein and further held itself out to such individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED FOURTEENTH:

That in reliance upon the foregoing, the plaintiff, Sonia Urriola, during a continuous course of treatment beginning on or about November 4, 2004 and ending on or about June 29, 2007 came under and/or submitted to the care and attention of the defendants LIOU, BIMC and BIMC-PHILLIPS.

ONE HUNDRED FIFTEENTH:

That at all times mentioned herein the plaintiff, Sonia Urriola, submitted to various tests, examinations, procedures, treatments and techniques, both oral and physical, performed by or at the special instance and request of the defendants and/or each of them, their agents, servants, associates, employees, and/or partners.

ONE HUNDRED SIXTEENTH:

That at all times mentioned herein, the defendants, their agents, servants, associates, partners and/or employees, were aware of or should have been aware of the results, import, findings and/or consequences of this history, complaints, signs, symptoms, pains, sensation and occurrences being experienced by the plaintiff, as well as the results, import, findings and/or consequences of the tests, examinations, procedure, treatments and/or techniques performed on the plaintiff, by the said defendants, their agents, servants, employees, associates and/or partners.

ONE HUNDRED SEVENTEENTH:

That in view of the foregoing, the course of treatment, advice, diagnosis, medical care and attention, prescriptions, tests, examinations, studies, surgery, pre and post surgical care, procedures and/or techniques given to and/or performed on the plaintiff by the defendants, their agents, servants, associates, partners and/or employees was not in accord with the accepted standards of the proper

practice of medicine, which are generally recognized within the local, state or national community.

ONE HUNDRED EIGHTEENTH:

That the defendants LIOU, BIMC and BIMC-PHILLIPS and/or each of them, individually, jointly and/or concurrently, their agents, servants, associates, partners and/or employees, by acts of commission and omission were negligent, careless and reckless and departed from accepted practices in the following areas:

- a. negligently, carelessly, and recklessly failed to properly monitor plaintiff after implanting a Contak Renewal 3HE, Model H179 in plaintiff;
- b. negligently, carelessly and recklessly failed to remove a defective implantable cardiac defibrillator in a timely fashion;
- c. failed and omitted to remove this device from the plaintiff's body before the device caused injury to plaintiff;
- d. failed to use appropriate precautionary measures to avoid infection and injury in the plaintiff's body as a result of a defective and dangerous implantable cardiac defibrillator they inserted in plaintiff;
- e. negligently, carelessly, and recklessly failed to attach appropriate significance to plaintiff's complaints of weakness;
- f. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of fatigue;
- g. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of difficulty walking;
- h. negligently, carelessly and recklessly failed to attach appropriate significance to

- plaintiff's complaints of difficulty climbing stairs;
- i. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of weight gain;
 - j. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of atypical body aches;
 - k. negligently, carelessly and recklessly failed and omitted to diagnose a massive fungal infection in plaintiff as a result of the Contak Renewal 3HE Model 179 ICD implanted in plaintiff;
 - l. caused and/or allowed the plaintiff to develop a massive infection of the defective ICD implanted in her body;
 - m. failed to maintain proper monitoring of plaintiff after being notified of the recall of the Contak Renewal 3HE Model H179 which was implanted in plaintiff;
 - n. failed and omitted to inform the plaintiff of the dangers and risks as well as alternatives;
 - o. failed and omitted to make a timely diagnosis of the plaintiff's condition;
 - p. failed and omitted to perform proper and timely tests, examinations, procedures, studies, surgery, pre and post surgical care, and in general in giving medical care, attention, treatment and/or care to the plaintiff;
 - q. failed and omitted to understand the clinical analysis, laboratory analysis, history, physical examination, complaints, pains, signs and/or symptoms so that a proper diagnosis could be made and/or a proper course of treatment given;
 - r. failed and omitted to conform to the accepted standards of care and skill in giving

advice, treatment, anesthesiology, prescriptions, examinations, information, services, surgery, pre and post surgical care, attention, studies, laboratory and radiological examinations and/or facts to the plaintiff herein;

- s. failed and omitted to use their best judgment and reasonable care in their medical care, attention, services, treatment, medication, diagnosis and other medical services rendered on behalf of the plaintiff.

ONE HUNDRED NINETEENTH:

That solely as a result of the negligence and/or medical malpractice of the defendants, and/or each of them, their agents, servants, associates, partners and/or employees, and without any negligence or culpable conduct on the part of the plaintiff contributing thereto, the plaintiff was caused to sustain the injuries which are hereinafter referred to.

ONE HUNDRED TWENTIETH:

That as a result of the negligence and/or medical malpractice, as aforesaid, the plaintiff, Sonia Urriola became, still is and for a long time to come will be sick, sore, lame, bruised, injured, and wounded in and about the various parts of her head, neck, lungs, body, limbs and shoulders, both internally and externally including various organs, functions of her body and including surrounding muscles, tissues, arteries, veins, blood vessels, cells, and other parts of plaintiff's body and that plaintiff also sustained psychological injuries and/or mental anguish and agony and was otherwise injured and upon information and belief said injuries are permanent; that by reason of the foregoing the plaintiff, Sonia Urriola as obliged to and did necessarily employ medical aid, medicinals, hospital aid and other treatment in an attempt to cure herself of said injuries and has been prevented from performing her duties and will be so prevented for a long time to come.

ONE HUNDRED TWENTY FIRST:

That by reason of the foregoing departures from accepted medical practice, the plaintiff, Sonia Urriola, has been damaged by the defendants herein and seeks a monetary award and damages which exceed the jurisdictional limits of all lower courts which would otherwise have jurisdiction over the defendants herein.

**AS AND FOR A NINTH CAUSE OF ACTION TO RECOVER
MONETARY DAMAGES FROM THE DEFENDANT UNDER A
THEORY OF LACK OF INFORMED CONSENT ON BEHALF
OF THE PLAINTIFF, SONIA Urriola**

ONE HUNDRED TWENTY SECOND:

That the plaintiff, Sonia Urriola, repeats, reiterates, and realleges each and every allegation of the Complaint, set forth in paragraphs "FIRST" through "ONE HUNDRED TWENTY FIRST" with the same force and effect as though said allegations were herein fully set forth at length.

ONE HUNDRED TWENTY THIRD:

That at all times mentioned herein, the defendants LIOU, BIMC and BIMC-PHILLIPS, their agents, servants, associates, partners, and/or employees negligently, carelessly and recklessly failed and omitted to make an understandable disclosure to the plaintiff of the surgery, diagnostic procedures, and/or invasive procedures, that said defendant was about to perform and/or did perform including but not limited to the dangers and risks to the plaintiff's health and/or life, whether or not the surgery, diagnostic procedure, or invasive procedures were ordinarily performed under the same conditions, whether or not other or different operations and/or procedures, if any, are and were used, and the manner in which the alternative operations and/or risks involved in the alternative operation and/or procedure.

ONE HUNDRED TWENTY FOURTH:

That had the defendants given accurate information disclosing the foregoing departures, risks, and/or alternatives, the plaintiff and/or a reasonably prudent person would have decided not to undergo the surgery, diagnostic procedure and/or invasive procedure at the time and under the circumstances then and there existing to the knowledge of the defendants.

ONE HUNDRED TWENTY FIFTH:

That the above described negligent failure and omission by the defendants to obtain a proper informed consent from the plaintiff led to various unauthorized invasions upon the plaintiff's body in the nature of unauthorized surgical procedures, diagnostic procedures and/or invasive procedures and that as such the defendants are responsible for the entire flow of damages and injury following said procedures.

ONE HUNDRED TWENTY SIXTH:

That as a result of the negligent failure and omission to obtain a proper informed consent, the plaintiff, Sonia Urriola, became, still is and for a long time to come will be sick, sore, lame, bruised, injured, and wounded in and about the various parts of her heart, lungs, his head, neck, abdomen, intestines, body and limbs, both internally and externally including various organs, functions of her body and including surrounding muscles, tissues, arteries, veins, blood vessels, cells, and other parts of plaintiff's body and that plaintiff also sustained psychological injuries and or mental anguish and agony and was otherwise injured and upon information and belief said injuries are permanent; that by reason of the foregoing the plaintiff, Sonia Urriola, was obliged to and did necessarily employ medical aid, medicinals, hospital aid and other treatment in an attempt to cure herself of said injuries and has been prevented from performing her duties and will be so prevented for a long time to come.

ONE HUNDRED TWENTY SEVENTH:

That as a result of the foregoing lack of informed consent the plaintiff, Sonia Urriola has been damaged by the defendants herein and seeks a monetary award and damages which exceed the jurisdictional limit of all lower Courts which would otherwise have jurisdiction over the defendants herein

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the First Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Second Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Third Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Fourth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Fifth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Sixth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Seventh Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

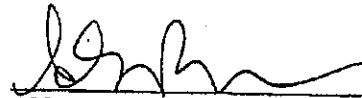
WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Eighth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Ninth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action; and

WHEREFORE, plaintiff, SONIA URRIOLA, demands a monetary judgement in the form of damages against the defendants and/or each of them herein together with the costs and disbursements of this action.

Dated: Brooklyn, New York
October 24 , 2007

I have read the foregoing and I certify that , upon information and belief, the source of which is the review of a file maintained by my office, that the foregoing is not frivolous as defined in subsection (c) of Section 130-1.1 of the Rules of the Chief Administrator.



ANDREA E. BONINA, ESQ.
BONINA & BONINA, P.C.
Attorneys for Plaintiff(s)
16 Court Street, Suite 1800
Brooklyn, New York 11241
(718) 522-1786

STATEMENT PURSUANT TO CPLR SECTION 3012-a(2)

I am an attorney duly licensed to practice law in the State of New York. I was unable to obtain the consultation required by CPLR Section 3012-a(1) because the Statute of Limitations is to expire in the very near future and would bar the action. The Certificate of Merit required by CPLR Section 3012-a(1) could not reasonably be obtained before such time expired. The Certificate of Merit required shall be served within 90 days after service of the Complaint.

A handwritten signature in black ink, appearing to read 'A. Bonina', is written over a horizontal line.

ANDREA E. BONINA, ESQ.

EXHIBIT 2

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SUMMONS

-----X
SONIA URRIOLA,

Index No.: 114306 /07

Date Purchased: 10/24/07

Plaintiffs,

Plaintiff designates New York
County as the place of trial.

-against-

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC CORPORATION,
MICHAEL LIU, M.D., BETH ISRAEL MEDICAL
CENTER AND BETH ISRAEL MEDICAL CENTER
PHILIPS AMBULATORY CARE CENTER,

The basis of venue is:

Plaintiff's Residence

Plaintiff resides at:

126 East 3rd Street, Apt. 3A
New York, New York 10009

Defendants,

County of New York
-----X

To the above named Defendants:

You are hereby summoned to answer the complaint in this action, and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance on the Plaintiff's attorneys within twenty days after the service of this summons, exclusive of the day of service, where service is made by delivery upon you personally within the state, or, within 30 days after completion of service where service is made in any other manner. In case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: Brooklyn, NY
October 24 , 2007



ANDREA E. BONINA, ESQ.

BONINA & BONINA, P.C.

Attorneys for Plaintiff - SONIA URRIOLA

16 Court Street, Suite 1800

Brooklyn, New York 11241

(718) 522-1786

ORIGINAL SUMMONS AND VERIFIED COMPLAINT FILED ON OCTOBER ____, 2007.

NEW YORK
COUNTY CLERK'S OFFICE

OCT 24 2007

NOT COMPARED
WITH COPY FILE

TO:

Dr. Michael Liou
c/o Beth Isreal Medical Center
10 Union Square East, Suite 2A
Phillips Ambulatory Care Center
New York, New York 10003

Beth Isreal Medical Center
307 First Avenue
New York, New York 10003

Beth Israel Medical Center - Phillips Ambulatory
10 Union Square East, Suite 2A
New York, New York 10003

Boston Scientific Co.
c/o Corporation Service Company
Albany, New York 12207

Guidant Sales Corporation
111 Monument Circle, #2900
Indianapolis Indiana 46204
Attention: Viki Williams

Guidant Sales Corporation
Corporation Service Company
80 State Street
Albany, New York 12207

Guidant
4100 Hamline Avenue North
St. Paul, Minnesota 55112

COMPLETE THIS STUB

Endorse This INDEX NUMBER ON All
Papers and advise your adversary of
the number assigned. Sec. 202.5,
Uniform Rules Of Trial Courts

DO NOT DETACH

Title of Action or Proceeding to be TYPED or PRINTED by applicant
SUPREME COURT, NEW YORK COUNTY

V.

INDEX NUMBER FEE
\$210.00

07114306

RECEIPT
NEW YORK COUNTY CLERK
60 CENTRE STREET
NEW YORK, NY 10007
R141

| DEPARTMENT | AMOUNT |
|--------------|---------------|
| 1 GEN | 165.00 |
| 7 SURCHARGE | 45.00 |
| TOTAL | 210.00 |
| CHECK | 210.00 |

| CONS | CASHIER | DATE | TIME | TERM |
|-------|---------|-----------|---------|------|
| 28746 | 1235 | 07 OCT 24 | 1:36 PM | 41-2 |

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

Plaintiffs,

VERIFIED COMPLAINT

-against-

Index No.: 114306 107

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC
CORPORATION, MICHAEL LIU, M.D., BETH
ISRAEL MEDICAL CENTER AND BETH ISRAEL
MEDICAL CENTER PHILIPS AMBULATORY CARE
CENTER,

Defendants,
-----X

Plaintiffs, by and through their attorneys, Bonina & Bonina, P.C., complaining of the
defendants herein, as and for their Verified Complaint in the above entitled action, respectfully show
to this Court and allege upon information and belief as follows:

**AS AND FOR A FIRST CAUSE OF ACTION ON BEHALF OF PLAINTIFF
SONIA URRIOLA TO RECOVER MONETARY DAMAGES FROM THE
DEFENDANTS UNDER A THEORY OF DEFECT IN DESIGN**

FIRST:

That prior to service of this Summons & Complaint and on the 24th day of October 2007,
plaintiffs have purchased Index No. _____/07 from the Supreme Court of the State of
New York, County of New York, in accordance with the requirements of the CPLR.

SECOND:

That this action falls within one or more exceptions set forth in CPLR §1602.

THIRD:

Plaintiffs demand a trial by jury.

FOURTH:

That all times mentioned herein, plaintiff, Sonia Urriola, is, was, and has been a resident of the County of New York, City and State of New York.

FIFTH:

That at all times mentioned herein, Defendant Guidant, (hereinafter Guidant) is a foreign corporation with its principal place of business in a state other than New York.

SIXTH:

Defendant Guidant manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model number H179.

SEVENTH:

That at all times herein mentioned, the Defendant Guidant, was and still is a foreign corporation duly authorized to do business in the State of New York.

EIGHTH:

That at all times mentioned herein, Defendant Guidant, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

NINTH:

That at all times mentioned herein, Defendant Guidant Sales Corporation, (hereinafter Guidant Sales) is a foreign corporation with its principal place of business in a state other than New York.

TENTH:

Defendant Guidant Sales manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain implantable Cardiac Resynchronization Therapy - Defibrillators (CRT-D) and including the Contak Renewal 3HE Model number H179.

ELEVENTH:

That at all times herein mentioned, the Defendant Guidant Sales, was and still is a foreign corporation duly authorized to do business in the State of New York.

TWELFTH:

That at all times mentioned herein, Defendant Guidant Sales, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

THIRTEENTH:

That at all times mentioned herein, defendant Boston Scientific Corporation (hereinafter Boston) is a corporation incorporated pursuant to the laws of the State of Delaware and has its principal place of business in Massachusetts.

FOURTEENTH:

Defendant Boston manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 4HE Model number H179.

FIFTEENTH:

That at all times mentioned herein, the Defendant Boston, was and still is a domestic corporation duly organized and existing under and by virtue of the laws of the State of New York.

SIXTEENTH:

That at all times mentioned herein, the Defendant Boston, was and still is a foreign corporation duly authorized to do business in the State of New York.

SEVENTEENTH:

That at all times mentioned herein, Defendant Boston, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

EIGHTEENTH:

That at all times mentioned herein Defendant Boston, is, was and has been a limited partnership or limited liability company duly organized under and existing by virtue of the laws of the State of New York.

NINETEENTH:

That upon information and belief the defendant Boston has acquired or merged with the defendant Guidant and/or defendant Guidant Sales and is a successor in interest to all claims articulated herein and stated against defendants Guidant and Guidant Sales.

TWENTIETH:

At all times, defendants were engaged in the business of manufacturing, selling, distributing, promoting, designing and testing Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179.

TWENTY FIRST:

Each defendant placed the Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179, into the stream of commerce and derived substantial benefits from this product which was sold for profit in the State of New York by the

defendants, their agents, servants, associates, subsidiaries, partners and/or employees.

TWENTY SECOND:

At all times hereinafter mentioned all of the above named defendants regularly did and/or transacted and/or solicited business in the State of New York or were engaged in other persistent courses of conduct or derived substantial revenue from goods used or consumed or services rendered in the State of New York.

TWENTY THIRD:

That at all times mentioned herein the defendants expected or should have reasonably expected its acts to have consequences within the State of New York, and derived and continues to derive substantial revenue from Interstate and International Commerce.

TWENTY FOURTH:

That at all times mentioned herein, defendants held themselves out to the general public, and more particularly to the plaintiff herein, as duly qualified and/or capable of manufacturing designing, testing, distributing, promoting and/or selling safe and proper implantable medical devices, including but not limited to the Contak Renewal 3HE Model H179 within the State of New York.

TWENTY FIFTH:

That at all times mentioned herein, the defendants for consideration held themselves out as distributing, manufacturing, designing and selling proper, adequate and safe implantable medical devices, namely the Contak Renewal 3HE Model H179 to members of the general public and more particularly plaintiff herein, and further held themselves out to such individuals as having the necessary skills, expertise, training, and/or personnel, equipment and supplies to perform the same up to the standards of such care prevalent within the Local, State, and National Community.

TWENTY SIXTH:

At all times mentioned herein, defendants themselves, or by use of others did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, advertise, warn, and otherwise distribute in interstate commerce the Contak Renewal 3HE Model H179.

TWENTY SEVENTH:

The Contak Renewal 3HE Model H179 was widely advertised by the defendants in the State of New York and throughout the United States for use by persons with irregular cardiac rhythms.

TWENTY EIGHTH:

Upon information and belief the defendant manufactured an implantable device named the Contak Renewal 3HE Model H179, which was designed, manufactured, marketed, tested, distributed and sold for profit in the State of New York by one or more of the defendants herein.

TWENTY NINTH:

At all times relevant herein, the defendants were engaged in the business of manufacturing, marketing, promoting, selling, distributing and placing in the stream of commerce an implantable cardiac defibrillator device known as the Contak Renewal 3HE Model H179. Upon information and belief each defendant engaged in advertising and promotional activity which indicated its product was efficacious and safe to use and, that based upon the defendants promotional activity with respect to the aforesaid product, said product was implanted into the plaintiff's body based upon the belief that the same was safe to use and was unlikely to subject the plaintiff to any serious danger or injury as a result of the use of the product.

THIRTIETH:

That the aforesaid Product was and is sold to hospitals and physicians for implantation into patients who are at risk for having life threatening arrhythmia's as a result of electro physiological changes in the hearts rhythms resulting in a change in heart rhythm, which are life threatening if the patient does not receive an electrical shock from an appropriate device.

THIRTY FIRST:

Defendant's aforesaid Product contains wires, called leads, inserted through blood vessels and attached to the heart to detect irregularity in the hearts rhythm and to deliver an electrical shock to prevent or terminate an arrhythmia.

THIRTY SECOND:

In on or about November 4, 2004, the plaintiff Sonia Urriola underwent surgery for the implantation of a Guidant Contak Renewal 3HE Model H179 cardiac defibrillator with serial number 504858.

THIRTY THIRD:

Upon information and belief, the Guidant Contak Renewal 3HE Model H179 was manufactured, promoted, and marketed by the defendants, and/or each of them, as a safe medical device that would be beneficial for cardiac patients at risk for arrhythmia.

THIRTY FOURTH:

Upon information and belief, defendants and/or each of them were in control of the design, manufacture testing, labeling, warning, product information, packaging, promoting, assembly, manufacture, marketing, distribution and/or sales the aforementioned implantable cardiac defibrillator.

THIRTY FIFTH:

Defendants made filings with the United States Food and Drug Administration (hereinafter referred to as FDA) in conjunction with the approval process for the Contak Renewal 3HE Model H179.

THIRTY SIXTH:

Defendants promoted the Guidant Contak Renewal 3HE Model 179 as a therapy to reduce the risk of hospitalization or death and as a device that could relieve symptoms associated with heart failure, including shortness of breath and fatigue.

THIRTY SEVENTH:

That said Contak Renewal 3HE Model H179 came equipped with certain standard equipment, including, among other things, certain wires and/or leads which were improperly and/or inadequately insulated.

THIRTY EIGHTH:

That said Contak Renewal 3HE Model H179, came equipped with certain standard equipment, including, among other things, certain and/or switches which were improperly and/or inadequately manufactured and were prone to stitching.

THIRTY NINTH:

That the Contak Renewal 3HE Model 179 came equipped with certain standard equipment including among other things, low voltage capacitors which were subject to degradation.

FORTIETH:

That said wires and/or leads and/or seals and/or low voltage capacitors were an integral and inherent part of the safety equipment of the above referenced Contak Renewal 3HE Model H179, the

purpose of which was to provide proper protection to the ordinary and foreseeable users and consumers of said device.

FORTY FIRST:

Sonia Urriola had a Guidant Contak Renewal 3HE Model 179 Serial number 504858 implanted on or about November 4, 2004 and it remained implanted until on or about June 29, 2007.

FORTY SECOND:

Subsequent to having the Guidant Contak Renewal 4HE Model 179 implanted plaintiff, Sonia Urriola, suffered from physical and emotional injuries and severely diminished quality of life and life expectancy and was caused to and will be caused to expend sums of money for medical care and monitoring.

FORTY THIRD:

The product warnings in effect between October 2005 and June 2007 were both substantially and wholly inadequate to alert prescribing physicians and consumer patients of the risk of injury and infection associated with the Guidant Contak Renewal 3HE Model H179 which were then known to the defendants.

FORTY FOURTH:

Defendants had a duty to exercise reasonable care in the design manufacture, testing, clinical trials, compiling of product information, submission of product information to FDA, pre- and post-marketing testing, sale, marketing and/or distribution of Guidant Contak Renewal 3HE Model H179 into the stream of commerce, including a duty to insure the product did not cause users to suffer from unreasonable and dangerous side effects and injuries as a result of having the product implanted.

FORTY FIFTH:

Defendants failed to exercise ordinary care in the manufacturing, selling, testing, quality assurance, quality control and/or distribution of Guidant Contak Renewal 3HE Model 179 into interstate commerce in that defendants knew or reasonably should have known that the product created an increased risk for unreasonable dangerous side effects some of which could only be alleviated by invasive and/or surgical procedures, and some of which can be fatal.

FORTY SIXTH:

Defendants and/or each of them, and/or their agents, servants, subsidiaries, partners, associates and employees, acted negligently, carelessly and recklessly, and in willful and wanton disregard for the health, life and safety of their consumers and the public, with respect to their distribution, manufacture, testing, marketing, advertising, and sale of the Contak Renewal 3HE Model H179 in the following ways:

- a. Negligently, carelessly and recklessly manufactured, constructed, engineered, inspected, marketed, tested, and sold implantable cardiac devices that included a seal that leaked allowing moisture to damage electrical components;
- b. Negligently, carelessly and recklessly designed, constructed, engineered, inspected, marketed, tested and sold implantable cardiac devices that included a seal that stuck allowing moisture to damage electrical components;
- c. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant injury;
- d. Failed to adequately and timely advise consumers and healthcare providers of the

dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant life threatening infections;

- e. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators, including the Contak Renewal 3HE Model 179, that had leads and/or wires that were not properly insulated;
- f. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators that had inadequate insulation material on the leads and/or the wires causing these parts of the Contak Renewal 3HE Model H179 to have an increased risk of degradation;
- g. Manufactured, constructed, engineered, inspected, distributed, marketed, tested and sold implantable cardiac defibrillators which were a significant risk of injury to consumers, and in particular to the plaintiff herein;
- h. Knew or reasonably should have known of the potential serious side effects, including but not limited to infection and surgical intervention, and failed to properly investigate and research these issues in clinical trials;
- i. Knew or reasonably of should have known of the potential serious side effects including but not limited to infection and the need for surgical intervention and failed to properly investigate and perform/post sale and adequate post marketing follow up studies;
- j. Failed and omitted to provide adequate information to medical professionals regarding the risks associated with the implantation of Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179;

- k. Failed and/or omitted to inform medical professionals of the significant risk of infection as a result of degradation of the leads/wires;
- l. Manufactured, constructed, distributed, marketed, inspected, tested, and sold a implantable cardiac defibrillator which was unsafe and unfit for its reasonable, ordinary and foreseeable uses;
- m. Caused, allowed and permitted a dangerous defective and unsuitable product to be marketed to the medical profession for use in patients who were medically dependent upon a properly working defibrillator;
- n. Failed to adequately warn members of the medical profession of the risks and dangers inherent in the insertion and use of the Contak Renewal 3HE implantable cardiac defibrillator Model 179;
- o. Failed and/or omitted to properly test the device to determine its effectiveness, and the effectiveness of the insulation on the leads/wires;
- p. Failed and/or omitted to properly instruct members of the medical profession as to the proper manner of testing the device, as well as the proper methods of monitoring patients for defects in the device;
- q. Failed and omitted to properly design, manufacture, assemble, sell, distribute and promote a product that members of the public, including the plaintiff herein, relied upon to sustain life;
- r. Failed and omitted to exercise reasonable and ordinary care and due diligence in ascertaining the defective condition and improper design and manufacturing defects in the Contak Renewal 3E Model H179 implantable cardiac defibrillator;

- s. Failed and omitted to protect the public interest and more particularly that of the plaintiff herein;
- t. Manufactured, distributed, engineered, delivered, sold and marketed an implantable cardiac defibrillator which was inherently dangerous to the life and health of the public, its intended and foreseeable users and more particularly to the plaintiff herein;
- u. Failed and omitted to adopt and enforce proper inspection and testing techniques procedures and protocols on each and every cardiac defibrillator designed, manufactured, constructed, engineered, assembled, sold and distributed including the Contak Renewal 3HE Model H179;
- v. Failed and omitted to properly and adequately notify members of the medical profession regarding the defects present in the Contak Renewal 3HE Model H179 cardiac defibrillator; and
- w. Failed and omitted to institute proper, adequate and timely recall procedures.

FORTY SEVENTH:

As a result of defendants' defectively designed Cardiac Resynchronization Therapy - Defibrillators (CRT-D), plaintiff required surgery and extensive rehabilitation and suffered serious infection as a result of the Contak Renewal 3HE Model H179.

FORTY EIGHTH:

As a result of the above referenced conduct of the defendants and/or their subsidiaries, successors and interests, divisions, agents, servants, associates, partners and/or employees, the plaintiff Sonia Urriola was caused to suffer a significant and life threatening infection which required the removal of her implantable cardiac defibrillator as well as extensive hospitalization thereafter, and

she became and still is, and for a long time to come, will be sick, sore, lame, bruised, injured, wounded, and disabled in the various parts of her head, body, and plaintiff otherwise sustains psychological injuries, and upon information and belief all the aforementioned injuries are permanent. By reason of the foregoing the plaintiff, Sonia Urriola was obliged to and did necessarily employ hospital aid, medical aid, medicinals, surgical intervention, rehabilitation services and medical supplies in an attempt to cure herself of her injuries, and she has been prevented from performing her usual duties and will be so prevented for a long time to come.

FORTY NINTH:

That the plaintiff is not seeking to recover any damages for which plaintiff has been reimbursed by insurance or other applicable coverage. Plaintiff is only seeking to recover those damages not recoverable through insurance and/or other applicable coverage under the facts and circumstances in this action.

FIFTIETH:

That as a result of the aforementioned, the plaintiff Sonia Urriola, has been damaged in an amount exceeding all jurisdictional limits of the lower Courts.

**AS AND FOR A SECOND CAUSE OF ACTION ON BEHALF OF
THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY OF
STRICT PRODUCTS LIABILITY FOR A DEFECT IN MANUFACTURE**

FIFTY FIRST:

That the Plaintiff, SONIA URRIOLA, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "FIFTIETH", with the same force and effect as though said allegations were here and fully set forth at length.

FIFTY SECOND:

That reasonable reliance upon the proper function of said Contak Renewal 3HE Model H179 device, the plaintiff, Sonia Urriola had said Contak Renewal 3HE Model H179 implanted on or about November 4, 2004.

FIFTY THIRD:

That, while the plaintiff had said device implanted as aforesaid, said device caused serious and severe injuries to the Plaintiff herein, including but not limited to massive fungal infection.

FIFTY FOURTH:

That, upon information and belief, the happening of the occurrence as aforesaid was the result of defects in manufacture, which caused the Plaintiff to suffer and sustain serious and severe injuries.

FIFTY FIFTH:

That, at all times mention herein, the Defendants knew and/or reasonably should have known the intended use to which said Contak Renewal 3HE Model H179 and its appurtenances would be put, and that the general public, and more particularly the Plaintiff herein, would be involved in said uses.

FIFTY SIXTH:

That, at all times mentioned herein, the Defendants and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, failed to exercise the proper and reasonable degree of care in the manufacturing, assembling, sterilizing, engineering, and insertion of the Contak Renewal 3HE Model H179, causing said Contak Renewal 3HE Model H179 to be dangerously defective, and not reasonably safe for its ordinary, intended and foreseeable purposes.

FIFTY SEVENTH:

Defendants and/or each of them, and/or their agents, servants, partners, associates and employees, acted negligently, carelessly and recklessly, and in willful and wanton disregard for the health, life and safety of their consumers and the public, with respect to their distribution, manufacture, testing, marketing, advertising, and sale of the Contak Renewal 3HE Model H179 in the following ways:

- a. Negligently, carelessly and recklessly manufactured, constructed, engineered, inspected, marketed, tested, and sold implantable cardiac devices that included a seal that leaked allowing moisture to damage electrical components;
- b. Negligently, carelessly and recklessly designed, constructed, engineered, inspected, marketed, tested and sold implantable cardiac devices that included a seal that stuck allowing moisture to damage electrical components;
- c. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant injury;
- d. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant life threatening infections;
- e. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators, including the Contak Renewal 3HE Model 179, that had leads and/or wires that were not properly insulated;
- f. Manufactured, constructed, engineered, inspected, marketed, tested and sold

implantable cardiac defibrillators that had inadequate insulation material on the leads and/or the wires causing these parts of the Contak Renewal 3HE Model H179 to have an increased risk of degradation;

- g. Manufactured, constructed, engineered, inspected, distributed, marketed, tested and sold implantable cardiac defibrillators which were a significant risk of injury to consumers, and in particular to the plaintiff herein;
- h. Knew or reasonably should have known of the potential serious side effects, including but not limited to infection and surgical intervention, and failed to properly investigate and research these issues in clinical trials;
- i. Knew or reasonably should have known of the potential serious side effects including but not limited to infection and the need for surgical intervention and failed to properly investigate and perform/post sale and adequate post marketing follow up studies;
- j. Failed and omitted to provide adequate information to medical professionals regarding the risks associated with the implantation of Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179;
- k. Failed and/or omitted to inform medical professionals of the significant risk of infection as a result of degradation of the leads/wires;
- l. Manufactured, constructed, distributed, marketed, inspected, tested, and sold a implantable cardiac defibrillator which was unsafe and unfit for its reasonable, ordinary and foreseeable uses;
- m. Caused, allowed and permitted a dangerous defective and unsuitable product to be

marketed to the medical profession for use in patients who were medically dependent upon a properly working defibrillator;

- n. Failed to adequately warn members of the medical profession of the risks and dangers inherent in the insertion and use of the Contak Renewal 3HE implantable cardiac defibrillator Model 179;
- o. Failed and/or omitted to properly test the device to determine its effectiveness, and the effectiveness of the insulation on the leads/wires;
- p. Failed and/or omitted to properly instruct members of the medical profession as to the proper manner of testing the device, as well as the proper methods of monitoring patients for defects in the device;
- q. Failed and omitted to properly design, manufacture, assemble, sell, distribute and promote a product that members of the public, including the plaintiff herein, relied upon to sustain life;
- r. Failed and omitted to exercise reasonable and ordinary care and due diligence in ascertaining the defective condition and improper design and manufacturing defects in the Contak Renewal 3E Model H179 implantable cardiac defibrillator;
- s. Failed and omitted to protect the public interest and more particularly that of the plaintiff herein;
- t. Manufactured, distributed, engineered, delivered, sold and marketed an implantable cardiac defibrillator which was inherently dangerous to the life and health of the public, its intended and foreseeable users and more particularly to the plaintiff herein;
- u. Failed and omitted to adopt and enforce proper inspection and testing techniques,

procedures and protocols on each and every cardiac defibrillator designed, manufactured, constructed, engineered, assembled, sold and distributed including the Contak Renewal 3HE Model H179;

v. Failed and omitted to properly and adequately notify members of the medical profession regarding the defects present in the Contak Renewal 3HE Model H179 cardiac defibrillator; and

w. Failed and omitted to institute proper, adequately and timely recall procedures.

FIFTY EIGHTH:

That as a result of the above referenced conduct of the Defendant, and/or its subsidiaries, divisions, successors in interest, agents, servants, associates, partners, and/or employees, the Plaintiff, Sonia Urriola, was caused to suffer a massive fungal infection requiring removal of the device and surgical interventions and became, still is, and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her body and said plaintiff otherwise sustained psychological injuries, and upon information and belief said injuries are permanent, that by reason of the foregoing, the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals, and medical supplies in an attempt to cure herself of said injuries, and has been prevented from performing her usual duties and will be so prevented for a long time to come.

FIFTY NINTH:

That by reason of the foregoing, the Plaintiff, Sonia Urriola, has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A THIRD CAUSE OF ACTION ON BEHALF OF
THE PLAINTIFF, SONIA URRIOLA, BASED UPON A
THEORY OF NEGLIGENCE**

SIXTIETH:

That the Plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "FIFTY EIGHTH", with the same force and effect as though said allegations were herein fully set forth at length.

SIXTY FIRST:

That on or about June 29, 2007 as a result of the insertion of Contak Renewal 3HE Model 179, the Plaintiff, Sonia Urriola, was caused to suffer a massive fungal infection requiring removal of the device and resulting in serious and severe injuries.

SIXTY SECOND:

That the aforementioned occurrence was caused wholly and exclusively as a result of the negligence, carelessness and recklessness of Defendants, and/or Defendants' divisions, successors in interest, subsidiaries, agents, servants, associates, partners, and/or employees without any negligence or culpable conduct on the part of the Plaintiff, Sonia Urriola, contributing thereto.

SIXTY THIRD:

That Defendants, and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, actually and/or reasonably knew or should have known at the time of the design and/or manufacture of the aforesaid Contak Renewal 3HE Model H179, that said device was dangerously defective, hazardous, unsafe, dangerous, and posed certain dangers and it was unfit for its ordinary, normal and foreseeable usages by intended users and/or operators.

SIXTY FOURTH:

That, upon information and belief, the happening of the occurrence as aforesaid was the result of the negligence, carelessness and recklessness of defendants, and/or each of them which caused the Plaintiff to suffer and sustain serious and severe injuries.

SIXTY FIFTH:

That, at all times mention herein, the Defendants knew and/or reasonably should have known the intended use to which said Contak Renewal 3HE Model 179 and its appurtenances would be put, and that the general public, and more particularly the Plaintiff herein, would be involved in said uses.

SIXTY SIXTH:

That, at all times mentioned herein, the Defendants and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, failed to exercise the proper and reasonable degree of care in the manufacturing, assembling, engineering, and inserting of the Contak Renewal 3HE Model 179, causing said Contak Renewal 3HE Model 179 to be dangerously defective, and not reasonably safe for its ordinary, intended and foreseeable purposes.

SIXTY SEVENTH:

That as a result of the above referenced conduct of the Defendants, and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, the Plaintiff, Sonia Urriola, was caused to suffer injuries and became, still is, and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her head, body, fingers, limbs, extremities, and hands, and said Plaintiff otherwise sustained psychological injuries, and upon information and belief said injuries are permanent, that by reason of the foregoing, the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals and medical

supplies in an attempt to cure himself of said injuries, and has been prevented from performing his usual duties and will be so prevented for a long time to come.

SIXTY EIGHTH:

That by reason of the foregoing, the Plaintiff, Sonia Urriola, has been damaged in a sum exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A FOURTH CAUSE OF ACTION ON BEHALF
OF THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY
OF BREACH OF EXPRESS WARRANTY**

SIXTY NINTH:

That the plaintiff, Sonia Urriola repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "SIXTY EIGHTH", with the same force and effect as though said allegations were herein and fully set forth at length.

SEVENTIETH:

Defendants expressly warranted to the plaintiff that the product which they designed, developed, manufactured and sold was of a merchantable quality, fit, safe and otherwise beneficial to the plaintiff's health and well being and that it would improve the quality of plaintiff's life.

SEVENTY FIRST:

Defendants' representations formed a part of the basis of the bargain and plaintiff, Sonia Urriola relied upon said representations in deciding to have the product implanted.

SEVENTY SECOND:

That the product implanted in the plaintiff was unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to the plaintiff, Sonia Urriola and did not operate as represented.

SEVENTY THIRD:

Through the sale of the product, the defendants and/or each of them are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

SEVENTY FOURTH:

Defendants breached the express warranty of merchantability in sale of the product to Sonia Urriola and said products was not fit for its ordinary purpose as described above.

SEVENTY FIFTH:

As a direct and proximate cause of the defendants breach of their express warranties described herein, the plaintiff, Sonia Urriola suffered an injury as alleged herein above.

SEVENTY SIXTH:

That by reason of the foregoing the plaintiff, Sonia Urriola has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A FIFTH CAUSE OF ACTION ON BEHALF
OF THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY
OF BREACH OF IMPLIED WARRANTY**

SEVENTY SEVENTH:

Plaintiff repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraphs "FIRST" through "SEVENTY SIXTH" with the same force and effect as those said allegations were herein fully set forth at length.

SEVENTY EIGHTH:

Defendants, and/or each of them, are in the business of manufacturing and/or supplying and/or placing into the stream of commerce for consumers implantable cardiac devices known as the Contak Renewal 3HE Model H179.

SEVENTY NINTH:

By placing the product into the stream of commerce, said defendants impliedly warranted that the product was of merchantable quality, and was fit and safe for its intended use and was fit for the particular purpose of protecting the plaintiff, Sonia Urriola from cardiac arrhythmia.

EIGHTIETH:

That the product was placed into the stream of commerce by said defendants and was unmerchantable, was not fit and was not safe for its intended use and not fit for the particular purpose intended.

EIGHTY FIRST:

That the defects in the product manufactured and/or supplied by the defendants were present at the time that the product left the hands of the defendants.

EIGHTY SECOND:

As a result, the defendants breached implied warranties for the product because said product was defective, unmerchantable, and not fit for its intended particular purpose.

EIGHTY THIRD:

The plaintiff Sonia Urriola was a foreseeable user of the product herein, and as a direct and proximate cause of the defendants' breach of implied warranty, she sustained serious, life threatening injuries.

EIGHTY FOURTH:

That by reason of the foregoing plaintiff Sonia Urriola damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A SIXTH CAUSE OF ACTION FOR
FRAUDULENT MISREPRESENTATION**

EIGHTY FIFTH:

That the plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraph "FIRST" through "EIGHTY FOURTH" with the same force and effect as those said allegations were herein fully set forth at length.

EIGHTY SIXTH:

That the defendants fraudulently and falsely represented to the medical community and to the plaintiff herein that their product had been tested and found to be safe and effective for patients with heart disease.

EIGHTY SEVENTH:

That the representations made by the defendants were in fact false.

EIGHTY EIGHTH:

That when said representations were made by the defendants that they knew those representations to be false and/or willfully, wantonly and recklessly disregarded whether the representations were true.

EIGHTY NINTH:

That these representations were made by the defendants and/or their successors in interest and/or each of them with the intent of defrauding and deceiving the plaintiff and the public in general and the medical community in particular to recommend, dispense and purchase the product all of which evidences callous, reckless, willful and depraved indifference to the health and safety and welfare of the injured plaintiff.

NINETIETH:

At the time that the aforesaid representations were made by the defendant that the injured plaintiff was unaware of the falsity of said representations and reasonably believe them to be true.

NINETY FIRST:

In reliance upon said representations the injured plaintiff was induced to and did have the product surgically implanted and thereafter sustained injury and damages as a result of the unsafe product.

NINETY SECOND:

That as a result of the defendant malicious, reckless and/or negligent conduct, the plaintiff Sonia Urriola was caused to suffer significant injuries and became and still is and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her body and that said plaintiff sustains psychological injuries and upon information and belief said injuries are permanent. By reason of the foregoing the plaintiff, Sonia Urriola was obliged to and unnecessarily did employ hospital aid, surgical intervention, medical aid, rehabilitation services and medical supplies in an attempt to cure herself of said injuries and has been prevented from performing her usual duties and will be still prevented for a long time to come.

NINETY THIRD:

That by reason of the foregoing plaintiff, Sonia Urriola has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A SEVENTH CAUSE OF ACTION FOR
FRAUDULENT CONCEALMENT WARRANTY**

NINETY FOURTH:

That the plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraph "FIRST" through "NINETY THIRD" with the same force and effect as those said allegations were herein fully set forth at length.

NINETY FIFTH:

That at all times during the course of dealings between the defendants and the injured plaintiff the defendants misrepresented that the product was safe for its intended use.

NINETY SIXTH:

The defendants knew that the representations were false as the defendants knew that there were problems with the Contak Renewal Model H179 and/or components thereof malfunctioning prior to implantation and/or injury.

NINETY SEVENTH:

That in representations to plaintiff and by withholding defect information from the FDA, thus preventing regulation, the defendants fraudulently concealed and intentionally omitted the aforesaid material information and that the product was not safe for use and was susceptible to malfunction; that the defendants were aware of the products danger and that the product was defective and that the defect caused malfunction that rendered the device useless for a period of time with the potential to cause death and severe injury and emotional distress and that the product was manufactured and designed negligently and that the product was manufactured and designed defectively and that the product was manufactured and designed improperly.

NINETY EIGHTH:

The defendants were under a duty to disclose to injured patients and their physicians, hospitals and medical providers the defective nature of their product and/or risks and dangers associated with it.

NINETY NINTH:

That the defendants had sole access to material facts concerning the defective nature of the product and the defect and the propensity to malfunction and cause serious and dangerous side effects including infection, and hence cause damage to the injured plaintiff.

ONE HUNDREDTH:

That the defendants' concealment and omission of material facts concerning the safety of the product were made purposely, willfully, wantonly, and/or recklessly to mislead injured patients and their physicians, hospital and medical providers into reliance, continued use of this product and actions thereon and to cause them to purchase this product and/or have them implanted.

ONE HUNDRED FIRST:

That the defendants knew that the patients, and in particular the plaintiff herein, and their physician, hospitals, medical providers had no way of determining the truth behind defendants' concealment and omissions and that these included material omissions of facts surrounding the product.

ONE HUNDRED SECOND:

Injured plaintiff, Sonia Urriola, as well as her doctors, health care providers and/or hospitals reasonably relied on defendants concealment and/or misstatement of fact.

ONE HUNDRED THIRD:

As a direct and proximate result of defendants malicious, reckless and/or negligent conduct the plaintiff, Sonia Urriola, suffered significant injuries that upon information and belief are permanent, and has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A EIGHTH CAUSE OF ACTION TO
RECOVER MONETARY DAMAGES FROM THE DEFENDANTS
UNDER A THEORY OF DEPARTURE FROM ACCEPTED MEDICAL
PRACTICE ON BEHALF OF THE PLAINTIFF, SONIA URRIOLA**

ONE HUNDRED FOURTH:

That the Plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "ONE HUNDRED THIRD", with the same force and effect as though said allegations were here and fully set forth at length.

ONE HUNDRED FIFTH:

That at all times mentioned herein, the defendant MICHAEL LIOU, M.D., hereinafter referred to as "LIOU", maintained offices for the practice of medicine within the County of New York, City and State of New York.

ONE HUNDRED SIXTH:

That at all times mentioned herein, the defendant "LIOU" held himself out to the general public and more particularly to the plaintiff herein as a duly qualified and/or licensed physician and/or surgeon capable of practicing medicine and/or surgery within the State of New York.

ONE HUNDRED SEVENTH:

That at all times mentioned herein the defendant "LIOU", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services,

radiology services, laboratory services, pharmacy services, diagnostic and treatment services, surgical services including pre operative and post operative services, anesthesia services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein, and further held himself out to such individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED EIGHTH:

At all times mentioned herein, the defendant BETH ISRAEL MEDICAL CENTER, hereinafter referred to as "BIMC" was and still is a corporation, duly existing pursuant to the laws of the State of New York, and doing business within the County of New York, City and State of New York.

ONE HUNDRED NINTH:

That at all times mentioned herein, the defendant "BIMC" owned, operated, supervised, maintained, and/or controlled certain premises within the County of New York, City and State of New York, for the care of sick and ailing persons, and for other individuals requiring medical care and attention, including the plaintiff herein.

ONE HUNDRED TENTH:

That at all times mentioned herein, the defendant "BIMC", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services, radiology services, laboratory services, pharmacy services, diagnostic and treatment services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein and further held itself out to such

individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED ELEVENTH:

At all times mentioned herein, the defendant BETH ISRAEL MEDICAL CENTER PHILLIPS AMBULATORY CARE CENTER, hereinafter referred to as "BIMC-PHILLIPS" was and still is a corporation, duly existing pursuant to the laws of the State of New York, and doing business within the County of New York, City and State of New York.

ONE HUNDRED TWELFTH:

That at all times mentioned herein, the defendant "BIMC-PHILLIPS" owned, operated, supervised, maintained, and/or controlled certain premises within the County of New York, City and State of New York, for the care of sick and ailing persons, and for other individuals requiring medical care and attention, including the plaintiff herein.

ONE HUNDRED THIRTEENTH:

That at all times mentioned herein, the defendant "BIMC-PHILLIPS", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services, radiology services, laboratory services, pharmacy services, diagnostic and treatment services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein and further held itself out to such individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED FOURTEENTH:

That in reliance upon the foregoing, the plaintiff, Sonia Urriola, during a continuous course of treatment beginning on or about November 4, 2004 and ending on or about June 29, 2007 came under and/or submitted to the care and attention of the defendants LIOU, BIMC and BIMC-PHILLIPS.

ONE HUNDRED FIFTEENTH:

That at all times mentioned herein the plaintiff, Sonia Urriola, submitted to various tests, examinations, procedures, treatments and techniques, both oral and physical, performed by or at the special instance and request of the defendants and/or each of them, their agents, servants, associates, employees, and/or partners.

ONE HUNDRED SIXTEENTH:

That at all times mentioned herein, the defendants, their agents, servants, associates, partners and/or employees, were aware of or should have been aware of the results, import, findings and/or consequences of this history, complaints, signs, symptoms, pains, sensation and occurrences being experienced by the plaintiff, as well as the results, import, findings and/or consequences of the tests, examinations, procedure, treatments and/or techniques performed on the plaintiff, by the said defendants, their agents, servants, employees, associates and/or partners.

ONE HUNDRED SEVENTEENTH:

That in view of the foregoing, the course of treatment, advice, diagnosis, medical care and attention, prescriptions, tests, examinations, studies, surgery, pre and post surgical care, procedures and/or techniques given to and/or performed on the plaintiff by the defendants, their agents, servants, associates, partners and/or employees was not in accord with the accepted standards of the proper

practice of medicine, which are generally recognized within the local, state or national community.

ONE HUNDRED EIGHTEENTH:

That the defendants LIOU, BIMC and BIMC-PHILLIPS and/or each of them, individually, jointly and/or concurrently, their agents, servants, associates, partners and/or employees, by acts of commission and omission were negligent, careless and reckless and departed from accepted practices in the following areas:

- a. negligently, carelessly, and recklessly failed to properly monitor plaintiff after implanting a Contak Renewal 3HE, Model H179 in plaintiff;
- b. negligently, carelessly and recklessly failed to remove a defective implantable cardiac defibrillator in a timely fashion;
- c. failed and omitted to remove this device from the plaintiff's body before the device caused injury to plaintiff;
- d. failed to use appropriate precautionary measures to avoid infection and injury in the plaintiff's body as a result of a defective and dangerous implantable cardiac defibrillator they inserted in plaintiff;
- e. negligently, carelessly, and recklessly failed to attach appropriate significance to plaintiff's complaints of weakness;
- f. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of fatigue;
- g. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of difficulty walking;
- h. negligently, carelessly and recklessly failed to attach appropriate significance to

- plaintiff's complaints of difficulty climbing stairs;
- i. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of weight gain;
 - j. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of atypical body aches;
 - k. negligently, carelessly and recklessly failed and omitted to diagnose a massive fungal infection in plaintiff as a result of the Contak Renewal 3HE Model 179 ICD implanted in plaintiff;
 - l. caused and/or allowed the plaintiff to develop a massive infection of the defective ICD implanted in her body;
 - m. failed to maintain proper monitoring of plaintiff after being notified of the recall of the Contak Renewal 3HE Model H179 which was implanted in plaintiff;
 - n. failed and omitted to inform the plaintiff of the dangers and risks as well as alternatives;
 - o. failed and omitted to make a timely diagnosis of the plaintiff's condition;
 - p. failed and omitted to perform proper and timely tests, examinations, procedures, studies, surgery, pre and post surgical care, and in general in giving medical care, attention, treatment and/or care to the plaintiff;
 - q. failed and omitted to understand the clinical analysis, laboratory analysis, history, physical examination, complaints, pains, signs and/or symptoms so that a proper diagnosis could be made and/or a proper course of treatment given;
 - r. failed and omitted to conform to the accepted standards of care and skill in giving

advice, treatment, anesthesiology, prescriptions, examinations, information, services, surgery, pre and post surgical care, attention, studies, laboratory and radiological examinations and/or facts to the plaintiff herein;

- s. failed and omitted to use their best judgment and reasonable care in their medical care, attention, services, treatment, medication, diagnosis and other medical services rendered on behalf of the plaintiff.

ONE HUNDRED NINETEENTH:

That solely as a result of the negligence and/or medical malpractice of the defendants, and/or each of them, their agents, servants, associates, partners and/or employees, and without any negligence or culpable conduct on the part of the plaintiff contributing thereto, the plaintiff was caused to sustain the injuries which are hereinafter referred to.

ONE HUNDRED TWENTIETH:

That as a result of the negligence and/or medical malpractice, as aforesaid, the plaintiff, Sonia Urriola became, still is and for a long time to come will be sick, sore, lame, bruised, injured, and wounded in and about the various parts of her head, neck, lungs, body, limbs and shoulders, both internally and externally including various organs, functions of her body and including surrounding muscles, tissues, arteries, veins, blood vessels, cells, and other parts of plaintiff's body and that plaintiff also sustained psychological injuries and/or mental anguish and agony and was otherwise injured and upon information and belief said injuries are permanent; that by reason of the foregoing the plaintiff, Sonia Urriola as obliged to and did necessarily employ medical aid, medicinals, hospital aid and other treatment in an attempt to cure herself of said injuries and has been prevented from performing her duties and will be so prevented for a long time to come.

ONE HUNDRED TWENTY FIRST:

That by reason of the foregoing departures from accepted medical practice, the plaintiff, Sonia Urriola, has been damaged by the defendants herein and seeks a monetary award and damages which exceed the jurisdictional limits of all lower courts which would otherwise have jurisdiction over the defendants herein.

**AS AND FOR A NINTH CAUSE OF ACTION TO RECOVER
MONETARY DAMAGES FROM THE DEFENDANT UNDER A
THEORY OF LACK OF INFORMED CONSENT ON BEHALF
OF THE PLAINTIFF, SONIA Urriola**

ONE HUNDRED TWENTY SECOND:

That the plaintiff, Sonia Urriola, repeats, reiterates, and realleges each and every allegation of the Complaint, set forth in paragraphs "FIRST" through "ONE HUNDRED TWENTY FIRST" with the same force and effect as though said allegations were herein fully set forth at length.

ONE HUNDRED TWENTY THIRD:

That at all times mentioned herein, the defendants LIOU, BIMC and BIMC-PHILLIPS, their agents, servants, associates, partners, and/or employees negligently, carelessly and recklessly failed and omitted to make an understandable disclosure to the plaintiff of the surgery, diagnostic procedures, and/or invasive procedures, that said defendant was about to perform and/or did perform including but not limited to the dangers and risks to the plaintiff's health and/or life, whether or not the surgery, diagnostic procedure, or invasive procedures were ordinarily performed under the same conditions, whether or not other or different operations and/or procedures, if any, are and were used, and the manner in which the alternative operations and/or risks involved in the alternative operation and/or procedure.

ONE HUNDRED TWENTY FOURTH:

That had the defendants given accurate information disclosing the foregoing departures, risks, and/or alternatives, the plaintiff and/or a reasonably prudent person would have decided not to undergo the surgery, diagnostic procedure and/or invasive procedure at the time and under the circumstances then and there existing to the knowledge of the defendants.

ONE HUNDRED TWENTY FIFTH:

That the above described negligent failure and omission by the defendants to obtain a proper informed consent from the plaintiff led to various unauthorized invasions upon the plaintiff's body in the nature of unauthorized surgical procedures, diagnostic procedures and/or invasive procedures and that as such the defendants are responsible for the entire flow of damages and injury following said procedures.

ONE HUNDRED TWENTY SIXTH:

That as a result of the negligent failure and omission to obtain a proper informed consent, the plaintiff, Sonia Urriola, became, still is and for a long time to come will be sick, sore, lame, bruised, injured, and wounded in and about the various parts of her heart, lungs, his head, neck, abdomen, intestines, body and limbs, both internally and externally including various organs, functions of her body and including surrounding muscles, tissues, arteries, veins, blood vessels, cells, and other parts of plaintiff's body and that plaintiff also sustained psychological injuries and or mental anguish and agony and was otherwise injured and upon information and belief said injuries are permanent; that by reason of the foregoing the plaintiff, Sonia Urriola, was obliged to and did necessarily employ medical aid, medicinals, hospital aid and other treatment in an attempt to cure herself of said injuries and has been prevented from performing her duties and will be so prevented for a long time to come.

ONE HUNDRED TWENTY SEVENTH:

That as a result of the foregoing lack of informed consent the plaintiff, Sonia Urriola has been damaged by the defendants herein and seeks a monetary award and damages which exceed the jurisdictional limit of all lower Courts which would otherwise have jurisdiction over the defendants herein

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the First Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Second Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Third Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Fourth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Fifth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Sixth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Seventh Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

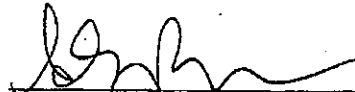
WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Eighth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Ninth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action; and

WHEREFORE, plaintiff, SONIA URRIOLO, demands a monetary judgement in the form of damages against the defendants and/or each of them herein together with the costs and disbursements of this action.

Dated: Brooklyn, New York
October 24 , 2007

I have read the foregoing and I certify that , upon information and belief, the source of which is the review of a file maintained by my office, that the foregoing is not frivolous as defined in subsection (c) of Section 130-1.1 of the Rules of the Chief Administrator.



ANDREA E. BONINA, ESQ.
BONINA & BONINA, P.C.
Attorneys for Plaintiff(s)
16 Court Street, Suite 1800
Brooklyn, New York 11241
(718) 522-1786

STATEMENT PURSUANT TO CPLR SECTION 3012-a(2)

I am an attorney duly licensed to practice law in the State of New York. I was unable to obtain the consultation required by CPLR Section 3012-a(1) because the Statute of Limitations is to expire in the very near future and would bar the action. The Certificate of Merit required by CPLR Section 3012-a(1) could not reasonably be obtained before such time expired. The Certificate of Merit required shall be served within 90 days after service of the Complaint.

A handwritten signature in black ink, appearing to read "A. Bonina", is written over a horizontal line.

ANDREA E. BONINA, ESQ.

STATE OF NEW YORK, COUNTY OF

ss.:

I, the undersigned, am an attorney admitted to practice in the courts of New York, and

Check Applicable Box

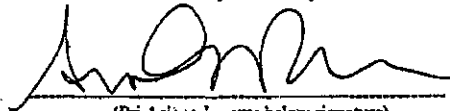
☐ Attorney's Certification

☐ Attorney's Verification By Affirmation

certify that the annexed has been compared by me with the original and found to be a true and complete copy thereof. say that: I am the attorney of record, or of counsel with the attorney(s) of record, for

I have read the annexed **SUMMONS, VERIFIED COMPLAINT AND CERTIFICATE OF MERIT** now the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on information and belief, and as to those matters I believe them to be true. My belief, as to those matters therein not stated upon knowledge, is based on the following. The review of a file maintained in my office

The reason I make this affirmation instead of Plaintiffs is that Plaintiffs reside outside the county where my office is maintained.

Dated: OCTOBER 24, 2007


(Print signer's name below signature)
ANDREA E. BONINA, ESQ.

STATE OF NEW YORK, COUNTY OF KINGS

ss.:

, being sworn says: I am the plaintiff

Check Applicable Box

☐ Individual Verification

☐ Corporate Verification

in the action herein; I have read the annexed

know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on information and belief, and as to those matters I believe them to be true. the of

a corporation, one of the parties to the action; I have read the annexed know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on information and belief, and as to those matters I believe them to be true. My belief, as to those matters therein not stated upon knowledge, is based on the following:

Sworn to before me on

(Print signer's name below signature)

STATE OF NEW YORK, COUNTY OF

ss.:

On

, being sworn says: I am not a party to the action, am over the age of 18 years of age and reside at
, I served a true copy of the annexed in the following manner:

☐ Service by Mail

by mailing the same in a sealed envelope, with postage prepaid thereon, in a post-office or official depository of the U.S. Postal Service within the State of New York, addressed to the last know address of the addressee(s) as indicated below:

☐ Personal Service

by delivering the same personally to the persons and at the addresses indicated below:

☐ Service by Electronic Means

by transmitting the same to the attorney by electronic means to the telephone number or other station or other limitation designated by the attorney for that purpose. In doing so I received a signal from the equipment of the attorney indicating that the transmission was received, and mailed a copy of same to that attorney, in a sealed envelope, with postage prepaid thereon, in a post office or official depository of the U.S. Postal Service within the State of New York, addressed to the last known address of the addressee(s) as indicated below:

☐ Overnight Delivery Service

by depositing the same with an overnight delivery service in a wrapper proper addressed. Said delivery was made prior to the latest time designated by the overnight delivery service for overnight delivery. The address and delivery service are indicated below:

INDEX NO.: 114306/07

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SONIA URRIOLA,

Plaintiffs,

-against-

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON SCIENTIFIC CORPORATION, MICHAEL LIOU, M.D., BETH ISRAEL MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants,

SUMMONS, VERIFIED COMPLAINT AND CERTIFICATE OF MERIT

BONINA & BONINA, P.C.

Attorneys for Plaintiff(s)

16 Court Street, Suite 1800

Brooklyn, NY 11241

Tele. No.: (718) 522-1786

Fax No.: (718) 243-0414

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed documents are not frivolous.

Dated: OCTOBER 24, 2007

Signature

Print Signer's Name:

ANDREA E. BONINA, ESQ.

Service of a copy of the within

is hereby admitted.

Dated:

Attorney(s) for

PLEASE TAKE NOTICE

Check Applicable Box



NOTICE OF
ENTRY

that the within is a (certified) true copy of a
entered in the office of the clerk of the within named Court on



NOTICE OF
SETTLEMENT

that a of which the within is a true copy
will be presented for settlement to the Hon. one of the judges of the
within named Court, at Supreme, on

Dated:

BONINA & BONINA, P.C.

Attorneys for Plaintiff(s)

16 COURT STREET

BROOKLYN, N.Y. 11241

To:

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SUMMONS

-----X
SONIA URRIOLA,

Index No.: 114306 /07
Date Purchased: 10/24/07

Plaintiffs,

Plaintiff designates New York
County as the place of trial.

-against-

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, ~~BOSTON SCIENTIFIC CORPORATION,~~
MICHAEL LIU, M.D., BETH ISRAEL MEDICAL
CENTER AND BETH ISRAEL MEDICAL CENTER
PHILIPS AMBULATORY CARE CENTER,

The basis of venue is:
Plaintiff's Residence

Plaintiff resides at:
126 East 3rd Street, Apt. 3A
New York, New York 10009

Defendants,
-----X

County of New York

To the above named Defendants:

You are hereby summoned to answer the complaint in this action, and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance on the Plaintiff's attorneys within twenty days after the service of this summons, exclusive of the day of service, where service is made by delivery upon you personally within the state, or, within 30 days after completion of service where service is made in any other manner. In case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: Brooklyn, NY
October 24, 2007



ANDREA E. BONINA, ESQ.
BONINA & BONINA, P.C.
Attorneys for Plaintiff - SONIA URRIOLA
16 Court Street, Suite 1800
Brooklyn, New York 11241
(718) 522-1786

ORIGINAL SUMMONS AND VERIFIED COMPLAINT FILED ON OCTOBER _____, 2007.

NEW YORK
COUNTY CLERK'S OFFICE

OCT 24 2007

NOT COMPARED
WITH COPY FILE

TO:

Dr. Michael Liou
c/o Beth Isreal Medical Center
10 Union Square East, Suite 2A
Phillips Ambulatory Care Center
New York, New York 10003

Beth Isreal Medical Center
307 First Avenue
New York, New York 10003

Beth Israel Medical Center - Phillips Ambulatory
10 Union Square East, Suite 2A
New York, New York 10003

Boston Scientific Co.
c/o Corporation Service Company
Albany, New York 12207

Guidant Sales Corporation
111 Monument Circle, #2900
Indianapolis Indiana 46204
Attention: Viki Williams

Guidant Sales Corporation
Corporation Service Company
80 State Street
Albany, New York 12207

Guidant
4100 Hamline Avenue North
St. Paul, Minnesota 55112

COMPLETE THIS STUB

Endorse This INDEX NUMBER ON All
Papers and advise your adversary of
the number assigned. Sec. 202.5,
Uniform Rules Of Trial Courts

DO NOT DETACH

Title of Action or Proceeding to be TYPED or PRINTED by applicant
SUPREME COURT, NEW YORK COUNTY

V.

INDEX NUMBER FEE
\$210.00

C 7114306

RECEIPT
NEW YORK COUNTY CLERK
60 CENTRE STREET
NEW YORK, NY 10007
R141

| DEPARTMENT | AMOUNT |
|--------------|---------------|
| 1 GEN | 165.00 |
| 7 SURCHARGE | 45.00 |
| TOTAL | 210.00 |
| CHECK | 210.00 |

| CONS | CASHIER | DATE | TIME | TERM |
|-------|---------|-----------|---------|------|
| 28746 | 1235 | 07 OCT 24 | 1:36 PM | 41-2 |

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

Plaintiffs,

VERIFIED COMPLAINT

-against-

Index No.: 114306 /07

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC
CORPORATION, MICHAEL LIU, M.D., BETH
ISRAEL MEDICAL CENTER AND BETH ISRAEL
MEDICAL CENTER PHILIPS AMBULATORY CARE
CENTER,

Defendants,
-----X

Plaintiffs, by and through their attorneys, Bonina & Bonina, P.C., complaining of the
defendants herein, as and for their Verified Complaint in the above entitled action, respectfully show
to this Court and allege upon information and belief as follows:

**AS AND FOR A FIRST CAUSE OF ACTION ON BEHALF OF PLAINTIFF
SONIA URRIOLA TO RECOVER MONETARY DAMAGES FROM THE
DEFENDANTS UNDER A THEORY OF DEFECT IN DESIGN**

FIRST:

That prior to service of this Summons & Complaint and on the 24th day of October 2007,
plaintiffs have purchased Index No. _____/07 from the Supreme Court of the State of
New York, County of New York, in accordance with the requirements of the CPLR.

SECOND:

That this action falls within one or more exceptions set forth in CPLR §1602.

THIRD:

Plaintiffs demand a trial by jury.

FOURTH:

That all times mentioned herein, plaintiff, Sonia Urriola, is, was, and has been a resident of the County of New York, City and State of New York.

FIFTH:

That at all times mentioned herein, Defendant Guidant, (hereinafter Guidant) is a foreign corporation with its principal place of business in a state other than New York.

SIXTH:

Defendant Guidant manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model number H179.

SEVENTH:

That at all times herein mentioned, the Defendant Guidant, was and still is a foreign corporation duly authorized to do business in the State of New York.

EIGHTH:

That at all times mentioned herein, Defendant Guidant, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

NINTH:

That at all times mentioned herein, Defendant Guidant Sales Corporation, (hereinafter Guidant Sales) is a foreign corporation with its principal place of business in a state other than New York.

TENTH:

Defendant Guidant Sales manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain implantable Cardiac Resynchronization Therapy - Defibrillators (CRT-D) and including the Contak Renewal 3HE Model number H179.

ELEVENTH:

That at all times herein mentioned, the Defendant Guidant Sales, was and still is a foreign corporation duly authorized to do business in the State of New York.

TWELFTH:

That at all times mentioned herein, Defendant Guidant Sales, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

THIRTEENTH:

That at all times mentioned herein, defendant Boston Scientific Corporation (hereinafter Boston) is a corporation incorporated pursuant to the laws of the State of Delaware and has its principal place of business in Massachusetts.

FOURTEENTH:

Defendant Boston manufactured, marketed, tested, designed, distributed and sold for profit in New York State certain Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 4HE Model number H179.

FIFTEENTH:

That at all times mentioned herein, the Defendant Boston, was and still is a domestic corporation duly organized and existing under and by virtue of the laws of the State of New York.

SIXTEENTH:

That at all times mentioned herein, the Defendant Boston, was and still is a foreign corporation duly authorized to do business in the State of New York.

SEVENTEENTH:

That at all times mentioned herein, Defendant Boston, is, was, and has been an unauthorized foreign corporation or other foreign business entity.

EIGHTEENTH:

That at all times mentioned herein Defendant Boston, is, was and has been a limited partnership or limited liability company duly organized under and existing by virtue of the laws of the State of New York.

NINETEENTH:

That upon information and belief the defendant Boston has acquired or merged with the defendant Guidant and/or defendant Guidant Sales and is a successor in interest to all claims articulated herein and stated against defendants Guidant and Guidant Sales.

TWENTIETH:

At all times, defendants were engaged in the business of manufacturing, selling, distributing, promoting, designing and testing Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179.

TWENTY FIRST:

Each defendant placed the Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179, into the stream of commerce and derived substantial benefits from this product which was sold for profit in the State of New York by the

defendants, their agents, servants, associates, subsidiaries, partners and/or employees.

TWENTY SECOND:

At all times hereinafter mentioned all of the above named defendants regularly did and/or transacted and/or solicited business in the State of New York or were engaged in other persistent courses of conduct or derived substantial revenue from goods used or consumed or services rendered in the State of New York.

TWENTY THIRD:

That at all times mentioned herein the defendants expected or should have reasonably expected its acts to have consequences within the State of New York, and derived and continues to derive substantial revenue from Interstate and International Commerce.

TWENTY FOURTH:

That at all times mentioned herein, defendants held themselves out to the general public, and more particularly to the plaintiff herein, as duly qualified and/or capable of manufacturing designing, testing, distributing, promoting and/or selling safe and proper implantable medical devices, including but not limited to the Contak Renewal 3HE Model H179 within the State of New York.

TWENTY FIFTH:

That at all times mentioned herein, the defendants for consideration held themselves out as distributing, manufacturing, designing and selling proper, adequate and safe implantable medical devices, namely the Contak Renewal 3HE Model H179 to members of the general public and more particularly plaintiff herein, and further held themselves out to such individuals as having the necessary skills, expertise, training, and/or personnel, equipment and supplies to perform the same up to the standards of such care prevalent within the Local, State, and National Community.

TWENTY SIXTH:

At all times mentioned herein, defendants themselves, or by use of others did manufacture, create, design, test, label, sterilize, package, distribute, supply, market, advertise, warn, and otherwise distribute in interstate commerce the Contak Renewal 3HE Model H179.

TWENTY SEVENTH:

The Contak Renewal 3HE Model H179 was widely advertised by the defendants in the State of New York and throughout the United States for use by persons with irregular cardiac rhythms.

TWENTY EIGHTH:

Upon information and belief the defendant manufactured an implantable device named the Contak Renewal 3HE Model H179, which was designed, manufactured, marketed, tested, distributed and sold for profit in the State of New York by one or more of the defendants herein.

TWENTY NINTH:

At all times relevant herein, the defendants were engaged in the business of manufacturing, marketing, promoting, selling, distributing and placing in the stream of commerce an implantable cardiac defibrillator device known as the Contak Renewal 3HE Model H179. Upon information and belief each defendant engaged in advertising and promotional activity which indicated its product was efficacious and safe to use and, that based upon the defendants promotional activity with respect to the aforesaid product, said product was implanted into the plaintiff's body based upon the belief that the same was safe to use and was unlikely to subject the plaintiff to any serious danger or injury as a result of the use of the product.

THIRTIETH:

That the aforesaid Product was and is sold to hospitals and physicians for implantation into patients who are at risk for having life threatening arrhythmia's as a result of electro physiological changes in the hearts rhythms resulting in a change in heart rhythm, which are life threatening if the patient does not receive an electrical shock from an appropriate device.

THIRTY FIRST:

Defendant's aforesaid Product contains wires, called leads, inserted through blood vessels and attached to the heart to detect irregularity in the hearts rhythm and to deliver an electrical shock to prevent or terminate an arrhythmia.

THIRTY SECOND:

In on or about November 4, 2004, the plaintiff Sonia Urriola underwent surgery for the implantation of a Guidant Contak Renewal 3HE Model H179 cardiac defibrillator with serial number 504858.

THIRTY THIRD:

Upon information and belief, the Guidant Contak Renewal 3HE Model H179 was manufactured, promoted, and marketed by the defendants, and/or each of them, as a safe medical device that would be beneficial for cardiac patients at risk for arrhythmia.

THIRTY FOURTH:

Upon information and belief, defendants and/or each of them were in control of the design, manufacture testing, labeling, warning, product information, packaging, promoting, assembly, manufacture, marketing, distribution and/or sales the aforementioned implantable cardiac defibrillator.

THIRTY FIFTH:

Defendants made filings with the United States Food and Drug Administration (hereinafter referred to as FDA) in conjunction with the approval process for the Contak Renewal 3HE Model H179.

THIRTY SIXTH:

Defendants promoted the Guidant Contak Renewal 3HE Model 179 as a therapy to reduce the risk of hospitalization or death and as a device that could relieve symptoms associated with heart failure, including shortness of breath and fatigue.

THIRTY SEVENTH:

That said Contak Renewal 3HE Model H179 came equipped with certain standard equipment, including, among other things, certain wires and/or leads which were improperly and/or inadequately insulated.

THIRTY EIGHTH:

That said Contak Renewal 3HE Model H179, came equipped with certain standard equipment, including, among other things, certain and/or switches which were improperly and/or inadequately manufactured and were prone to stitching.

THIRTY NINTH:

That the Contak Renewal 3HE Model 179 came equipped with certain standard equipment including among other things, low voltage capacitors which were subject to degradation.

FORTIETH:

That said wires and/or leads and/or seals and/or low voltage capacitors were an integral and inherent part of the safety equipment of the above referenced Contak Renewal 3HE Model H179, the

purpose of which was to provide proper protection to the ordinary and foreseeable users and consumers of said device.

FORTY FIRST:

Sonia Urriola had a Guidant Contak Renewal 3HE Model 179 Serial number 504858 implanted on or about November 4, 2004 and it remained implanted until on or about June 29, 2007.

FORTY SECOND:

Subsequent to having the Guidant Contak Renewal 4HE Model 179 implanted plaintiff, Sonia Urriola, suffered from physical and emotional injuries and severely diminished quality of life and life expectancy and was caused to and will be caused to expend sums of money for medical care and monitoring.

FORTY THIRD:

The product warnings in effect between October 2005 and June 2007 were both substantially and wholly inadequate to alert prescribing physicians and consumer patients of the risk of injury and infection associated with the Guidant Contak Renewal 3HE Model H179 which were then known to the defendants.

FORTY FOURTH:

Defendants had a duty to exercise reasonable care in the design manufacture, testing, clinical trials, compiling of product information, submission of product information to FDA, pre- and post-marketing testing, sale, marketing and/or distribution of Guidant Contak Renewal 3HE Model H179 into the stream of commerce, including a duty to insure the product did not cause users to suffer from unreasonable and dangerous side effects and injuries as a result of having the product implanted.

FORTY FIFTH:

Defendants failed to exercise ordinary care in the manufacturing, selling, testing, quality assurance, quality control and/or distribution of Guidant Contak Renewal 3HE Model 179 into interstate commerce in that defendants knew or reasonably should have known that the product created an increased risk for unreasonable dangerous side effects some of which could only be alleviated by invasive and/or surgical procedures, and some of which can be fatal.

FORTY SIXTH:

Defendants and/or each of them, and/or their agents, servants, subsidiaries, partners, associates and employees, acted negligently, carelessly and recklessly, and in willful and wanton disregard for the health, life and safety of their consumers and the public, with respect to their distribution, manufacture, testing, marketing, advertising, and sale of the Contak Renewal 3HE Model H179 in the following ways:

- a. Negligently, carelessly and recklessly manufactured, constructed, engineered, inspected, marketed, tested, and sold implantable cardiac devices that included a seal that leaked allowing moisture to damage electrical components;
- b. Negligently, carelessly and recklessly designed, constructed, engineered, inspected, marketed, tested and sold implantable cardiac devices that included a seal that stuck allowing moisture to damage electrical components;
- c. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant injury;
- d. Failed to adequately and timely advise consumers and healthcare providers of the

dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant life threatening infections;

- e. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators, including the Contak Renewal 3HE Model 179, that had leads and/or wires that were not properly insulated;
- f. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators that had inadequate insulation material on the leads and/or the wires causing these parts of the Contak Renewal 3HE Model H179 to have an increased risk of degradation;
- g. Manufactured, constructed, engineered, inspected, distributed, marketed, tested and sold implantable cardiac defibrillators which were a significant risk of injury to consumers, and in particular to the plaintiff herein;
- h. Knew or reasonably should have known of the potential serious side effects, including but not limited to infection and surgical intervention, and failed to properly investigate and research these issues in clinical trials;
- i. Knew or reasonably of should have known of the potential serious side effects including but not limited to infection and the need for surgical intervention and failed to properly investigate and perform/post sale and adequate post marketing follow up studies;
- j. Failed and omitted to provide adequate information to medical professionals regarding the risks associated with the implantation of Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179;

- k. Failed and/or omitted to inform medical professionals of the significant risk of infection as a result of degradation of the leads/wires;
- l. Manufactured, constructed, distributed, marketed, inspected, tested, and sold a implantable cardiac defibrillator which was unsafe and unfit for its reasonable, ordinary and foreseeable uses;
- m. Caused, allowed and permitted a dangerous defective and unsuitable product to be marketed to the medical profession for use in patients who were medically dependent upon a properly working defibrillator;
- n. Failed to adequately warn members of the medical profession of the risks and dangers inherent in the insertion and use of the Contak Renewal 3HE implantable cardiac defibrillator Model 179;
- o. Failed and/or omitted to properly test the device to determine its effectiveness, and the effectiveness of the insulation on the leads/wires;
- p. Failed and/or omitted to properly instruct members of the medical profession as to the proper manner of testing the device, as well as the proper methods of monitoring patients for defects in the device;
- q. Failed and omitted to properly design, manufacture, assemble, sell, distribute and promote a product that members of the public, including the plaintiff herein, relied upon to sustain life;
- r. Failed and omitted to exercise reasonable and ordinary care and due diligence in ascertaining the defective condition and improper design and manufacturing defects in the Contak Renewal 3E Model H179 implantable cardiac defibrillator;

- s. Failed and omitted to protect the public interest and more particularly that of the plaintiff herein;
- t. Manufactured, distributed, engineered, delivered, sold and marketed an implantable cardiac defibrillator which was inherently dangerous to the life and health of the public, its intended and foreseeable users and more particularly to the plaintiff herein;
- u. Failed and omitted to adopt and enforce proper inspection and testing techniques procedures and protocols on each and every cardiac defibrillator designed, manufactured, constructed, engineered, assembled, sold and distributed including the Contak Renewal 3HE Model H179;
- v. Failed and omitted to properly and adequately notify members of the medical profession regarding the defects present in the Contak Renewal 3HE Model H179 cardiac defibrillator; and
- w. Failed and omitted to institute proper, adequate and timely recall procedures.

FORTY SEVENTH:

As a result of defendants' defectively designed Cardiac Resynchronization Therapy - Defibrillators (CRT-D), plaintiff required surgery and extensive rehabilitation and suffered serious infection as a result of the Contak Renewal 3HE Model H179.

FORTY EIGHTH:

As a result of the above referenced conduct of the defendants and/or their subsidiaries, successors and interests, divisions, agents, servants, associates, partners and/or employees, the plaintiff Sonia Urriola was caused to suffer a significant and life threatening infection which required the removal of her implantable cardiac defibrillator as well as extensive hospitalization thereafter, and

she became and still is, and for a long time to come, will be sick, sore, lame, bruised, injured, wounded, and disabled in the various parts of her head, body, and plaintiff otherwise sustains psychological injuries, and upon information and belief all the aforementioned injuries are permanent. By reason of the foregoing the plaintiff, Sonia Urriola was obliged to and did necessarily employ hospital aid, medical aid, medicinals, surgical intervention, rehabilitation services and medical supplies in an attempt to cure herself of her injuries, and she has been prevented from performing her usual duties and will be so prevented for a long time to come.

FORTY NINTH:

That the plaintiff is not seeking to recover any damages for which plaintiff has been reimbursed by insurance or other applicable coverage. Plaintiff is only seeking to recover those damages not recoverable through insurance and/or other applicable coverage under the facts and circumstances in this action.

FIFTIETH:

That as a result of the aforementioned, the plaintiff Sonia Urriola, has been damaged in an amount exceeding all jurisdictional limits of the lower Courts.

**AS AND FOR A SECOND CAUSE OF ACTION ON BEHALF OF
THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY OF
STRICT PRODUCTS LIABILITY FOR A DEFECT IN MANUFACTURE**

FIFTY FIRST:

That the Plaintiff, SONIA URRIOLA, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "FIFTIETH", with the same force and effect as though said allegations were here and fully set forth at length.

FIFTY SECOND:

That reasonable reliance upon the proper function of said Contak Renewal 3HE Model H179 device, the plaintiff, Sonia Urriola had said Contak Renewal 3HE Model H179 implanted on or about November 4, 2004.

FIFTY THIRD:

That, while the plaintiff had said device implanted as aforesaid, said device caused serious and severe injuries to the Plaintiff herein, including but not limited to massive fungal infection.

FIFTY FOURTH:

That, upon information and belief, the happening of the occurrence as aforesaid was the result of defects in manufacture, which caused the Plaintiff to suffer and sustain serious and severe injuries.

FIFTY FIFTH:

That, at all times mention herein, the Defendants knew and/or reasonably should have known the intended use to which said Contak Renewal 3HE Model H179 and its appurtenances would be put, and that the general public, and more particularly the Plaintiff herein, would be involved in said uses.

FIFTY SIXTH:

That, at all times mentioned herein, the Defendants and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, failed to exercise the proper and reasonable degree of care in the manufacturing, assembling, sterilizing, engineering, and insertion of the Contak Renewal 3HE Model H179, causing said Contak Renewal 3HE Model H179 to be dangerously defective, and not reasonably safe for its ordinary, intended and foreseeable purposes.

FIFTY SEVENTH:

Defendants and/or each of them, and/or their agents, servants, partners, associates and employees, acted negligently, carelessly and recklessly, and in willful and wanton disregard for the health, life and safety of their consumers and the public, with respect to their distribution, manufacture, testing, marketing, advertising, and sale of the Contak Renewal 3HE Model H179 in the following ways:

- a. Negligently, carelessly and recklessly manufactured, constructed, engineered, inspected, marketed, tested, and sold implantable cardiac devices that included a seal that leaked allowing moisture to damage electrical components;
- b. Negligently, carelessly and recklessly designed, constructed, engineered, inspected, marketed, tested and sold implantable cardiac devices that included a seal that stuck allowing moisture to damage electrical components;
- c. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant injury;
- d. Failed to adequately and timely advise consumers and healthcare providers of the dangers associated with the Contak Renewal 3HE Model H179, including the risk that leakage and/or sticking could cause significant life threatening infections;
- e. Manufactured, constructed, engineered, inspected, marketed, tested and sold implantable cardiac defibrillators, including the Contak Renewal 3HE Model 179, that had leads and/or wires that were not properly insulated;
- f. Manufactured, constructed, engineered, inspected, marketed, tested and sold

implantable cardiac defibrillators that had inadequate insulation material on the leads and/or the wires causing these parts of the Contak Renewal 3HE Model H179 to have an increased risk of degradation;

- g. Manufactured, constructed, engineered, inspected, distributed, marketed, tested and sold implantable cardiac defibrillators which were a significant risk of injury to consumers, and in particular to the plaintiff herein;
- h. Knew or reasonably should have known of the potential serious side effects, including but not limited to infection and surgical intervention, and failed to properly investigate and research these issues in clinical trials;
- i. Knew or reasonably should have known of the potential serious side effects including but not limited to infection and the need for surgical intervention and failed to properly investigate and perform/post sale and adequate post marketing follow up studies;
- j. Failed and omitted to provide adequate information to medical professionals regarding the risks associated with the implantation of Cardiac Resynchronization Therapy - Defibrillators (CRT-D) including the Contak Renewal 3HE Model H179;
- k. Failed and/or omitted to inform medical professionals of the significant risk of infection as a result of degradation of the leads/wires;
- l. Manufactured, constructed, distributed, marketed, inspected, tested, and sold a implantable cardiac defibrillator which was unsafe and unfit for its reasonable, ordinary and foreseeable uses;
- m. Caused, allowed and permitted a dangerous defective and unsuitable product to be

marketed to the medical profession for use in patients who were medically dependent upon a properly working defibrillator;

- n. Failed to adequately warn members of the medical profession of the risks and dangers inherent in the insertion and use of the Contak Renewal 3HE implantable cardiac defibrillator Model 179;
- o. Failed and/or omitted to properly test the device to determine its effectiveness, and the effectiveness of the insulation on the leads/wires;
- p. Failed and/or omitted to properly instruct members of the medical profession as to the proper manner of testing the device, as well as the proper methods of monitoring patients for defects in the device;
- q. Failed and omitted to properly design, manufacture, assemble, sell, distribute and promote a product that members of the public, including the plaintiff herein, relied upon to sustain life;
- r. Failed and omitted to exercise reasonable and ordinary care and due diligence in ascertaining the defective condition and improper design and manufacturing defects in the Contak Renewal 3E Model H179 implantable cardiac defibrillator;
- s. Failed and omitted to protect the public interest and more particularly that of the plaintiff herein;
- t. Manufactured, distributed, engineered, delivered, sold and marketed an implantable cardiac defibrillator which was inherently dangerous to the life and health of the public, its intended and foreseeable users and more particularly to the plaintiff herein;
- u. Failed and omitted to adopt and enforce proper inspection and testing techniques,

procedures and protocols on each and every cardiac defibrillator designed, manufactured, constructed, engineered, assembled, sold and distributed including the Contak Renewal 3HE Model H179;

v. Failed and omitted to properly and adequately notify members of the medical profession regarding the defects present in the Contak Renewal 3HE Model H179 cardiac defibrillator; and

w. Failed and omitted to institute proper, adequately and timely recall procedures.

FIFTY EIGHTH:

That as a result of the above referenced conduct of the Defendant, and/or its subsidiaries, divisions, successors in interest, agents, servants, associates, partners, and/or employees, the Plaintiff, Sonia Urriola, was caused to suffer a massive fungal infection requiring removal of the device and surgical interventions and became, still is, and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her body and said plaintiff otherwise sustained psychological injuries, and upon information and belief said injuries are permanent, that by reason of the foregoing, the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals, and medical supplies in an attempt to cure herself of said injuries, and has been prevented from performing her usual duties and will be so prevented for a long time to come.

FIFTY NINTH:

That by reason of the foregoing, the Plaintiff, Sonia Urriola, has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A THIRD CAUSE OF ACTION ON BEHALF OF
THE PLAINTIFF, SONIA URRIOLA, BASED UPON A
THEORY OF NEGLIGENCE**

SIXTIETH:

That the Plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "FIFTY EIGHTH", with the same force and effect as though said allegations were herein fully set forth at length.

SIXTY FIRST:

That on or about June 29, 2007 as a result of the insertion of Contak Renewal 3HE Model 179, the Plaintiff, Sonia Urriola, was caused to suffer a massive fungal infection requiring removal of the device and resulting in serious and severe injuries.

SIXTY SECOND:

That the aforementioned occurrence was caused wholly and exclusively as a result of the negligence, carelessness and recklessness of Defendants, and/or Defendants' divisions, successors in interest, subsidiaries, agents, servants, associates, partners, and/or employees without any negligence or culpable conduct on the part of the Plaintiff, Sonia Urriola, contributing thereto.

SIXTY THIRD:

That Defendants, and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, actually and/or reasonably knew or should have known at the time of the design and/or manufacture of the aforesaid Contak Renewal 3HE Model H179, that said device was dangerously defective, hazardous, unsafe, dangerous, and posed certain dangers and it was unfit for its ordinary, normal and foreseeable usages by intended users and/or operators.

SIXTY FOURTH:

That, upon information and belief, the happening of the occurrence as aforesaid was the result of the negligence, carelessness and recklessness of defendants, and/or each of them which caused the Plaintiff to suffer and sustain serious and severe injuries.

SIXTY FIFTH:

That, at all times mention herein, the Defendants knew and/or reasonably should have known the intended use to which said Contak Renewal 3HE Model 179 and its appurtenances would be put, and that the general public, and more particularly the Plaintiff herein, would be involved in said uses.

SIXTY SIXTH:

That, at all times mentioned herein, the Defendants and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, failed to exercise the proper and reasonable degree of care in the manufacturing, assembling, engineering, and inserting of the Contak Renewal 3HE Model 179, causing said Contak Renewal 3HE Model 179 to be dangerously defective, and not reasonably safe for its ordinary, intended and foreseeable purposes.

SIXTY SEVENTH:

That as a result of the above referenced conduct of the Defendants, and/or their subsidiaries, divisions, agents, servants, associates, partners, and/or employees, the Plaintiff, Sonia Urriola, was caused to suffer injuries and became, still is, and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her head, body, fingers, limbs, extremities, and hands, and said Plaintiff otherwise sustained psychological injuries, and upon information and belief said injuries are permanent, that by reason of the foregoing, the Plaintiff, Sonia Urriola, was obliged to and did necessarily employ hospital aid, medical aid, medicinals and medical

supplies in an attempt to cure himself of said injuries, and has been prevented from performing his usual duties and will be so prevented for a long time to come.

SIXTY EIGHTH:

That by reason of the foregoing, the Plaintiff, Sonia Urriola, has been damaged in a sum exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A FOURTH CAUSE OF ACTION ON BEHALF
OF THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY
OF BREACH OF EXPRESS WARRANTY**

SIXTY NINTH:

That the plaintiff, Sonia Urriola repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "SIXTY EIGHTH", with the same force and effect as though said allegations were herein and fully set forth at length.

SEVENTIETH:

Defendants expressly warranted to the plaintiff that the product which they designed, developed, manufactured and sold was of a merchantable quality, fit, safe and otherwise beneficial to the plaintiff's health and well being and that it would improve the quality of plaintiff's life.

SEVENTY FIRST:

Defendants' representations formed a part of the basis of the bargain and plaintiff, Sonia Urriola relied upon said representations in deciding to have the product implanted.

SEVENTY SECOND:

That the product implanted in the plaintiff was unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to the plaintiff, Sonia Urriola and did not operate as represented.

SEVENTY THIRD:

Through the sale of the product, the defendants and/or each of them are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

SEVENTY FOURTH:

Defendants breached the express warranty of merchantability in sale of the product to Sonia Urriola and said products was not fit for its ordinary purpose as described above.

SEVENTY FIFTH:

As a direct and proximate cause of the defendants breach of their express warranties described herein, the plaintiff, Sonia Urriola suffered an injury as alleged herein above.

SEVENTY SIXTH:

That by reason of the foregoing the plaintiff, Sonia Urriola has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A FIFTH CAUSE OF ACTION ON BEHALF
OF THE PLAINTIFF, SONIA URRIOLA, BASED UPON A THEORY
OF BREACH OF IMPLIED WARRANTY**

SEVENTY SEVENTH:

Plaintiff repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraphs "FIRST" through "SEVENTY SIXTH" with the same force and effect as those said allegations were herein fully set forth at length.

SEVENTY EIGHTH:

Defendants, and/or each of them, are in the business of manufacturing and/or supplying and/or placing into the stream of commerce for consumers implantable cardiac devices known as the Contak Renewal 3HE Model H179.

SEVENTY NINTH:

By placing the product into the stream of commerce, said defendants impliedly warranted that the product was of merchantable quality, and was fit and safe for its intended use and was fit for the particular purpose of protecting the plaintiff, Sonia Urriola from cardiac arrhythmia.

EIGHTIETH:

That the product was placed into the stream of commerce by said defendants and was unmerchantable, was not fit and was not safe for its intended use and not fit for the particular purpose intended.

EIGHTY FIRST:

That the defects in the product manufactured and/or supplied by the defendants were present at the time that the product left the hands of the defendants.

EIGHTY SECOND:

As a result, the defendants breached implied warranties for the product because said product was defective, unmerchantable, and not fit for its intended particular purpose.

EIGHTY THIRD:

The plaintiff Sonia Urriola was a foreseeable user of the product herein, and as a direct and proximate cause of the defendants' breach of implied warranty, she sustained serious, life threatening injuries.

EIGHTY FOURTH:

That by reason of the foregoing plaintiff Sonia Urriola damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A SIXTH CAUSE OF ACTION FOR
FRAUDULENT MISREPRESENTATION**

EIGHTY FIFTH:

That the plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraph "FIRST" through "EIGHTY FOURTH" with the same force and effect as those said allegations were herein fully set forth at length.

EIGHTY SIXTH:

That the defendants fraudulently and falsely represented to the medical community and to the plaintiff herein that their product had been tested and found to be safe and effective for patients with heart disease.

EIGHTY SEVENTH:

That the representations made by the defendants were in fact false.

EIGHTY EIGHTH:

That when said representations were made by the defendants that they knew those representations to be false and/or willfully, wantonly and recklessly disregarded whether the representations were true.

EIGHTY NINTH:

That these representations were made by the defendants and/or their successors in interest and/or each of them with the intent of defrauding and deceiving the plaintiff and the public in general and the medical community in particular to recommend, dispense and purchase the product all of which evidences callous, reckless, willful and depraved indifference to the health and safety and welfare of the injured plaintiff.

NINETIETH:

At the time that the aforesaid representations were made by the defendant that the injured plaintiff was unaware of the falsity of said representations and reasonably believe them to be true.

NINETY FIRST:

In reliance upon said representations the injured plaintiff was induced to and did have the product surgically implanted and thereafter sustained injury and damages as a result of the unsafe product.

NINETY SECOND:

That as a result of the defendant malicious, reckless and/or negligent conduct, the plaintiff Sonia Urriola was caused to suffer significant injuries and became and still is and for a long time to come will be sick, sore, lame, bruised, injured, wounded and disabled in and about the various parts of her body and that said plaintiff sustains psychological injuries and upon information and belief said injuries are permanent. By reason of the foregoing the plaintiff, Sonia Urriola was obliged to and unnecessarily did employ hospital aid, surgical intervention, medical aid, rehabilitation services and medical supplies in an attempt to cure herself of said injuries and has been prevented from performing her usual duties and will be still prevented for a long time to come.

NINETY THIRD:

That by reason of the foregoing plaintiff, Sonia Urriola has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A SEVENTH CAUSE OF ACTION FOR
FRAUDULENT CONCEALMENT WARRANTY**

NINETY FOURTH:

That the plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the complaint set forth in paragraph "FIRST" through "NINETY THIRD" with the same force and effect as those said allegations were herein fully set forth at length.

NINETY FIFTH:

That at all times during the course of dealings between the defendants and the injured plaintiff the defendants misrepresented that the product was safe for its intended use.

NINETY SIXTH:

The defendants knew that the representations were false as the defendants knew that there were problems with the Contak Renewal Model H179 and/or components thereof malfunctioning prior to implantation and/or injury.

NINETY SEVENTH:

That in representations to plaintiff and by withholding defect information from the FDA, thus preventing regulation, the defendants fraudulently concealed and intentionally omitted the aforesaid material information and that the product was not safe for use and was susceptible to malfunction; that the defendants were aware of the products danger and that the product was defective and that the defect caused malfunction that rendered the device useless for a period of time with the potential to cause death and severe injury and emotional distress and that the product was manufactured and designed negligently and that the product was manufactured and designed defectively and that the product was manufactured and designed improperly.

NINETY EIGHTH:

The defendants were under a duty to disclose to injured patients and their physicians, hospitals and medical providers the defective nature of their product and/or risks and dangers associated with it.

NINETY NINTH:

That the defendants had sole access to material facts concerning the defective nature of the product and the defect and the propensity to malfunction and cause serious and dangerous side effects including infection, and hence cause damage to the injured plaintiff.

ONE HUNDREDTH:

That the defendants' concealment and omission of material facts concerning the safety of the product were made purposely, willfully, wantonly, and/or recklessly to mislead injured patients and their physicians, hospital and medical providers into reliance, continued use of this product and actions thereon and to cause them to purchase this product and/or have them implanted.

ONE HUNDRED FIRST:

That the defendants knew that the patients, and in particular the plaintiff herein, and their physician, hospitals, medical providers had no way of determining the truth behind defendants' concealment and omissions and that these included material omissions of facts surrounding the product.

ONE HUNDRED SECOND:

Injured plaintiff, Sonia Urriola, as well as her doctors, health care providers and/or hospitals reasonably relied on defendants concealment and/or misstatement of fact.

ONE HUNDRED THIRD:

As a direct and proximate result of defendants malicious, reckless and/or negligent conduct the plaintiff, Sonia Urriola, suffered significant injuries that upon information and belief are permanent, and has been damaged in an amount exceeding the jurisdictional limits of all lower Courts.

**AS AND FOR A EIGHTH CAUSE OF ACTION TO
RECOVER MONETARY DAMAGES FROM THE DEFENDANTS
UNDER A THEORY OF DEPARTURE FROM ACCEPTED MEDICAL
PRACTICE ON BEHALF OF THE PLAINTIFF, SONIA URRIOLA**

ONE HUNDRED FOURTH:

That the Plaintiff, Sonia Urriola, repeats, reiterates and realleges each and every allegation of the Complaints set forth in paragraphs numbered "FIRST" through "ONE HUNDRED THIRD", with the same force and effect as though said allegations were here and fully set forth at length.

ONE HUNDRED FIFTH:

That at all times mentioned herein, the defendant MICHAEL LIOU, M.D., hereinafter referred to as "LIOU", maintained offices for the practice of medicine within the County of New York, City and State of New York.

ONE HUNDRED SIXTH:

That at all times mentioned herein, the defendant "LIOU" held himself out to the general public and more particularly to the plaintiff herein as a duly qualified and/or licensed physician and/or surgeon capable of practicing medicine and/or surgery within the State of New York.

ONE HUNDRED SEVENTH:

That at all times mentioned herein the defendant "LIOU", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services,

radiology services, laboratory services, pharmacy services, diagnostic and treatment services, surgical services including pre operative and post operative services, anesthesia services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein, and further held himself out to such individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED EIGHTH:

At all times mentioned herein, the defendant BETH ISRAEL MEDICAL CENTER, hereinafter referred to as "BIMC" was and still is a corporation, duly existing pursuant to the laws of the State of New York, and doing business within the County of New York, City and State of New York.

ONE HUNDRED NINTH:

That at all times mentioned herein, the defendant "BIMC" owned, operated, supervised, maintained, and/or controlled certain premises within the County of New York, City and State of New York, for the care of sick and ailing persons, and for other individuals requiring medical care and attention, including the plaintiff herein.

ONE HUNDRED TENTH:

That at all times mentioned herein, the defendant "BIMC", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services, radiology services, laboratory services, pharmacy services, diagnostic and treatment services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein and further held itself out to such

individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED ELEVENTH:

At all times mentioned herein, the defendant BETH ISRAEL MEDICAL CENTER PHILLIPS AMBULATORY CARE CENTER, hereinafter referred to as "BIMC-PHILLIPS" was and still is a corporation, duly existing pursuant to the laws of the State of New York, and doing business within the County of New York, City and State of New York.

ONE HUNDRED TWELFTH:

That at all times mentioned herein, the defendant "BIMC-PHILLIPS" owned, operated, supervised, maintained, and/or controlled certain premises within the County of New York, City and State of New York, for the care of sick and ailing persons, and for other individuals requiring medical care and attention, including the plaintiff herein.

ONE HUNDRED THIRTEENTH:

That at all times mentioned herein, the defendant "BIMC-PHILLIPS", for a consideration, offered to render competent and adequate medical services, nursing services, emergency room services, ambulance services, patient transportation services, operating room services, recovery room services, radiology services, laboratory services, pharmacy services, diagnostic and treatment services, and in general all necessary services to give proper, adequate, and competent medical care to members of the general public, and more particularly, the plaintiff herein and further held itself out to such individuals as having the necessary personnel, equipment, supplies and facilities to perform the same.

ONE HUNDRED FOURTEENTH:

That in reliance upon the foregoing, the plaintiff, Sonia Urriola, during a continuous course of treatment beginning on or about November 4, 2004 and ending on or about June 29, 2007 came under and/or submitted to the care and attention of the defendants LIOU, BIMC and BIMC-PHILLIPS.

ONE HUNDRED FIFTEENTH:

That at all times mentioned herein the plaintiff, Sonia Urriola, submitted to various tests, examinations, procedures, treatments and techniques, both oral and physical, performed by or at the special instance and request of the defendants and/or each of them, their agents, servants, associates, employees, and/or partners.

ONE HUNDRED SIXTEENTH:

That at all times mentioned herein, the defendants, their agents, servants, associates, partners and/or employees, were aware of or should have been aware of the results, import, findings and/or consequences of this history, complaints, signs, symptoms, pains, sensation and occurrences being experienced by the plaintiff, as well as the results, import, findings and/or consequences of the tests, examinations, procedure, treatments and/or techniques performed on the plaintiff, by the said defendants, their agents, servants, employees, associates and/or partners.

ONE HUNDRED SEVENTEENTH:

That in view of the foregoing, the course of treatment, advice, diagnosis, medical care and attention, prescriptions, tests, examinations, studies, surgery, pre and post surgical care, procedures and/or techniques given to and/or performed on the plaintiff by the defendants, their agents, servants, associates, partners and/or employees was not in accord with the accepted standards of the proper

practice of medicine, which are generally recognized within the local, state or national community.

ONE HUNDRED EIGHTEENTH:

That the defendants LIOU, BIMC and BIMC-PHILLIPS and/or each of them, individually, jointly and/or concurrently, their agents, servants, associates, partners and/or employees, by acts of commission and omission were negligent, careless and reckless and departed from accepted practices in the following areas:

- a. negligently, carelessly, and recklessly failed to properly monitor plaintiff after implanting a Contak Renewal 3HE, Model H179 in plaintiff;
- b. negligently, carelessly and recklessly failed to remove a defective implantable cardiac defibrillator in a timely fashion;
- c. failed and omitted to remove this device from the plaintiff's body before the device caused injury to plaintiff;
- d. failed to use appropriate precautionary measures to avoid infection and injury in the plaintiff's body as a result of a defective and dangerous implantable cardiac defibrillator they inserted in plaintiff;
- e. negligently, carelessly, and recklessly failed to attach appropriate significance to plaintiff's complaints of weakness;
- f. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of fatigue;
- g. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of difficulty walking;
- h. negligently, carelessly and recklessly failed to attach appropriate significance to

- plaintiff's complaints of difficulty climbing stairs;
- i. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of weight gain;
 - j. negligently, carelessly and recklessly failed to attach appropriate significance to plaintiff's complaints of atypical body aches;
 - k. negligently, carelessly and recklessly failed and omitted to diagnose a massive fungal infection in plaintiff as a result of the Contak Renewal 3HE Model 179 ICD implanted in plaintiff;
 - l. caused and/or allowed the plaintiff to develop a massive infection of the defective ICD implanted in her body;
 - m. failed to maintain proper monitoring of plaintiff after being notified of the recall of the Contak Renewal 3HE Model H179 which was implanted in plaintiff;
 - n. failed and omitted to inform the plaintiff of the dangers and risks as well as alternatives;
 - o. failed and omitted to make a timely diagnosis of the plaintiff's condition;
 - p. failed and omitted to perform proper and timely tests, examinations, procedures, studies, surgery, pre and post surgical care, and in general in giving medical care, attention, treatment and/or care to the plaintiff;
 - q. failed and omitted to understand the clinical analysis, laboratory analysis, history, physical examination, complaints, pains, signs and/or symptoms so that a proper diagnosis could be made and/or a proper course of treatment given;
 - r. failed and omitted to conform to the accepted standards of care and skill in giving

advice, treatment, anesthesiology, prescriptions, examinations, information, services, surgery, pre and post surgical care, attention, studies, laboratory and radiological examinations and/or facts to the plaintiff herein;

- s. failed and omitted to use their best judgment and reasonable care in their medical care, attention, services, treatment, medication, diagnosis and other medical services rendered on behalf of the plaintiff.

ONE HUNDRED NINETEENTH:

That solely as a result of the negligence and/or medical malpractice of the defendants, and/or each of them, their agents, servants, associates, partners and/or employees, and without any negligence or culpable conduct on the part of the plaintiff contributing thereto, the plaintiff was caused to sustain the injuries which are hereinafter referred to.

ONE HUNDRED TWENTIETH:

That as a result of the negligence and/or medical malpractice, as aforesaid, the plaintiff, Sonia Urriola became, still is and for a long time to come will be sick, sore, lame, bruised, injured, and wounded in and about the various parts of her head, neck, lungs, body, limbs and shoulders, both internally and externally including various organs, functions of her body and including surrounding muscles, tissues, arteries, veins, blood vessels, cells, and other parts of plaintiff's body and that plaintiff also sustained psychological injuries and/or mental anguish and agony and was otherwise injured and upon information and belief said injuries are permanent; that by reason of the foregoing the plaintiff, Sonia Urriola as obliged to and did necessarily employ medical aid, medicinals, hospital aid and other treatment in an attempt to cure herself of said injuries and has been prevented from performing her duties and will be so prevented for a long time to come.

ONE HUNDRED TWENTY FIRST:

That by reason of the foregoing departures from accepted medical practice, the plaintiff, Sonia Urriola, has been damaged by the defendants herein and seeks a monetary award and damages which exceed the jurisdictional limits of all lower courts which would otherwise have jurisdiction over the defendants herein.

**AS AND FOR A NINTH CAUSE OF ACTION TO RECOVER
MONETARY DAMAGES FROM THE DEFENDANT UNDER A
THEORY OF LACK OF INFORMED CONSENT ON BEHALF
OF THE PLAINTIFF, SONIA Urriola**

ONE HUNDRED TWENTY SECOND:

That the plaintiff, Sonia Urriola, repeats, reiterates, and realleges each and every allegation of the Complaint, set forth in paragraphs "FIRST" through "ONE HUNDRED TWENTY FIRST" with the same force and effect as though said allegations were herein fully set forth at length.

ONE HUNDRED TWENTY THIRD:

That at all times mentioned herein, the defendants LIOU, BIMC and BIMC-PHILLIPS, their agents, servants, associates, partners, and/or employees negligently, carelessly and recklessly failed and omitted to make an understandable disclosure to the plaintiff of the surgery, diagnostic procedures, and/or invasive procedures, that said defendant was about to perform and/or did perform including but not limited to the dangers and risks to the plaintiff's health and/or life, whether or not the surgery, diagnostic procedure, or invasive procedures were ordinarily performed under the same conditions, whether or not other or different operations and/or procedures, if any, are and were used, and the manner in which the alternative operations and/or risks involved in the alternative operation and/or procedure.

ONE HUNDRED TWENTY FOURTH:

That had the defendants given accurate information disclosing the foregoing departures, risks, and/or alternatives, the plaintiff and/or a reasonably prudent person would have decided not to undergo the surgery, diagnostic procedure and/or invasive procedure at the time and under the circumstances then and there existing to the knowledge of the defendants.

ONE HUNDRED TWENTY FIFTH:

That the above described negligent failure and omission by the defendants to obtain a proper informed consent from the plaintiff led to various unauthorized invasions upon the plaintiff's body in the nature of unauthorized surgical procedures, diagnostic procedures and/or invasive procedures and that as such the defendants are responsible for the entire flow of damages and injury following said procedures.

ONE HUNDRED TWENTY SIXTH:

That as a result of the negligent failure and omission to obtain a proper informed consent, the plaintiff, Sonia Urriola, became, still is and for a long time to come will be sick, sore, lame, bruised, injured, and wounded in and about the various parts of her heart, lungs, his head, neck, abdomen, intestines, body and limbs, both internally and externally including various organs, functions of her body and including surrounding muscles, tissues, arteries, veins, blood vessels, cells, and other parts of plaintiff's body and that plaintiff also sustained psychological injuries and or mental anguish and agony and was otherwise injured and upon information and belief said injuries are permanent; that by reason of the foregoing the plaintiff, Sonia Urriola, was obliged to and did necessarily employ medical aid, medicinals, hospital aid and other treatment in an attempt to cure herself of said injuries and has been prevented from performing her duties and will be so prevented for a long time to come.

ONE HUNDRED TWENTY SEVENTH:

That as a result of the foregoing lack of informed consent the plaintiff, Sonia Urriola has been damaged by the defendants herein and seeks a monetary award and damages which exceed the jurisdictional limit of all lower Courts which would otherwise have jurisdiction over the defendants herein

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the First Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Second Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Third Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Fourth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Fifth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Sixth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Seventh Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

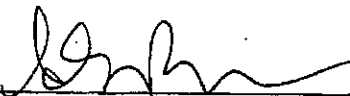
WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Eighth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action;

WHEREFORE, plaintiff, Sonia Urriola, demands a monetary judgement in the form of damages against the defendants and/or each of them herein on the Ninth Cause of Action, in an amount which exceeds the jurisdictional limits of all lower Courts which would otherwise have jurisdiction of this action; and

WHEREFORE, plaintiff, SONIA URRIOLA, demands a monetary judgement in the form of damages against the defendants and/or each of them herein together with the costs and disbursements of this action.

Dated: Brooklyn, New York
October 24 , 2007

I have read the foregoing and I certify that , upon information and belief, the source of which is the review of a file maintained by my office, that the foregoing is not frivolous as defined in subsection (c) of Section 130-1.1 of the Rules of the Chief Administrator.



ANDREA E. BONINA, ESQ.
BONINA & BONINA, P.C.
Attorneys for Plaintiff(s)
16 Court Street, Suite 1800
Brooklyn, New York 11241
(718) 522-1786

STATEMENT PURSUANT TO CPLR SECTION 3012-a(2)

I am an attorney duly licensed to practice law in the State of New York. I was unable to obtain the consultation required by CPLR Section 3012-a(1) because the Statute of Limitations is to expire in the very near future and would bar the action. The Certificate of Merit required by CPLR Section 3012-a(1) could not reasonably be obtained before such time expired. The Certificate of Merit required shall be served within 90 days after service of the Complaint.

A handwritten signature in black ink, appearing to read 'A. Bonina', is written over a horizontal line.

ANDREA E. BONINA, ESQ.

STATE OF NEW YORK, COUNTY OF

ss.:

I, the undersigned, am an attorney admitted to practice in the courts of New York, and

Check Applicable Box

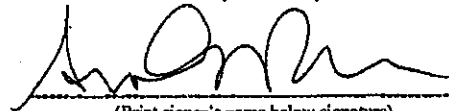
☐ Attorney's
Certification

certify that the annexed
has been compared by me with the original and found to be a true and complete copy thereof.
say that: I am the attorney of record, or of counsel with the attorney(s) of record, for

☒ Attorney's
Verification
By
Affirmation

I have read the annexed **SUMMONS, VERIFIED COMPLAINT AND CERTIFICATE OF MERIT** now the contents thereof
and the same are true to my knowledge, except those matters therein which are stated to be alleged on information and belief, and as
to those matters I believe them to be true. My belief, as to those matters therein not stated upon knowledge, is based on
on the following. The review of a file maintained in my office

The reason I make this affirmation instead of Plaintiffs is that Plaintiffs reside outside the county where my
office is maintained.

Dated: OCTOBER 24, 2007


(Print signer's name below signature)
ANDREA E. BONINA, ESQ.

STATE OF NEW YORK, COUNTY OF KINGS

ss.:

, being sworn says: I am the plaintiff

Check Applicable Box

☐ Individual
Verification

☐ Corporate
Verification

in the action herein; I have read the annexed
know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged on
information and belief, and as to those matters I believe them to be true.
the of

a corporation, one of the parties to the action; I have read the annexed
know the contents thereof and the same are true to my knowledge, except those matters therein which are stated to be alleged
on information and belief, and as to those matters I believe them to be true. My belief, as to those matters therein not stated upon
knowledge, is based on the following:

Sworn to before me on

(Print signer's name below signature)

STATE OF NEW YORK, COUNTY OF

ss.:

On , being sworn says: I am not a party to the action, am over the age of 18 years of age and reside at
I served a true copy of the annexed in the following manner:

☐ Service
by Mail

by mailing the same in a sealed envelope, with postage prepaid thereon, in a post-office or official depository of the U.S.
Postal Service within the State of New York, addressed to the last know address of the addressee(s) as indicated below:

☐ Personal
Service

by delivering the same personally to the persons and at the addresses indicated below:

☐ Service by
Electronic
Means

by transmitting the same to the attorney by electronic means to the telephone number or other station or other limitation
designated by the attorney for that purpose. In doing so I received a signal from the equipment of the attorney indicating that
the transmission was received, and mailed a copy of same to that attorney, in a sealed envelope, with postage prepaid thereon,
in a post office or official depository of the U.S. Postal Service within the State of New York, addressed to the last known
address of the addressee(s) as indicated below:

☐ Overnight
Delivery
Service

by depositing the same with an overnight delivery service in a wrapper proper addressed. Said delivery was made prior to the
latest time designated by the overnight delivery service for overnight delivery. The address and delivery service are indicated
below:

INDEX NO.: 114306/07

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SONIA URRIOLA,

Plaintiffs,

-against-

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON SCIENTIFIC CORPORATION, MICHAEL LIOU, M.D., BETH ISRAEL MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants,

SUMMONS, VERIFIED COMPLAINT AND CERTIFICATE OF MERIT

BONINA & BONINA, P.C.

Attorneys for Plaintiff(s)

16 Court Street, Suite 1800

Brooklyn, NY 11241

Tele. No.: (718) 522-1786

Fax No.: (718) 243-0414

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed documents are not frivolous.

Dated: OCTOBER 24, 2007

Signature

Print Signer's Name:

ANDREA E. BONINA, ESQ.

Service of a copy of the within

is hereby admitted.

Dated:

Attorney(s) for

PLEASE TAKE NOTICE

Check Applicable Box

☐
NOTICE OF
ENTRY

that the within is a (certified) true copy of a
entered in the office of the clerk of the within named Court on

☐
NOTICE OF
SETTLEMENT

that a of which the within is a true copy
will be presented for settlement to the Hon. one of the judges of the
within named Court, at Supreme, on

Dated:

BONINA & BONINA, P.C.
Attorneys for Plaintiff(s)
16 COURT STREET
BROOKLYN, N.Y. 11241

To:

EXHIBIT 3

UNITED STATES DISTRICT COURT *Small*

MIDDLE DISTRICT OF FLORIDA, Tampa Division 0100-4 File 3:20

IN RE: FEN-PHEN CASES

CASE NUMBERS:

8:01-CV-1587-T-30-MAP
8:01-CV-1589-T-30-MAP
8:01-CV-1591-T-30-MSS
8:01-CV-1592-T-30-TBM
8:01-CV-1593-T-30-TGW
8:01-CV-1594-T-30-EAJ
8:01-CV-1595-T-30-EAJ
8:01-CV-1597-T-30-MAP
8:01-CV-1598-T-30-EAJ
8:01-CV-1599-T-30-TBM
8:01-CV-1603-T-30-MAP
8:01-CV-1604-T-30-TGW
8:01-CV-1605-T-30-MAP
8:01-CV-1606-T-30-EAJ
8:01-CV-1607-T-30-MAP
8:01-CV-1608-T-30-MSS
8:01-CV-1610-T-30-TBM
8:01-CV-1611-T-30-TBM
8:01-CV-1612-T-30-EAJ
8:01-CV-1613-T-30-MSS
8:01-CV-1614-T-30-TGW

8:01-CV-1615-T-30-TBM
8:01-CV-1616-T-30-MAP
8:01-CV-1618-T-30-TBM
8:01-CV-1619-T-30-TBM
8:01-CV-1620-T-30-TBM
8:01-CV-1622-T-30-MAP
8:01-CV-1624-T-30-MSS
8:01-CV-1625-T-30-TBM
8:01-CV-1626-T-30-MSS
8:01-CV-1628-T-30-EAJ
8:01-CV-1629-T-30-MSS
8:01-CV-1630-T-30-EAJ
8:01-CV-1631-T-30-TBM
8:01-CV-1634-T-30-MSS
8:01-CV-1635-T-30-TGW
8:01-CV-1673-T-30-MAP
8:01-CV-1674-T-30-TGW
8:01-CV-1675-T-30-TBM
8:01-CV-1677-T-30-MSS
8:01-CV-1678-T-30-MSS
8:01-CV-1679-T-30-MSS

8:01-CV-1680-T-30-TBM
8:01-CV-1681-T-30-MAP
8:01-CV-1682-T-30-MAP
8:01-CV-1683-T-30-TBM
8:01-CV-1684-T-30-EAJ
8:01-CV-1685-T-30-MAP
8:01-CV-1686-T-30-EAJ
8:01-CV-1688-T-30-EAJ
8:01-CV-1689-T-30-EAJ
8:01-CV-1690-T-30-EAJ
8:01-CV-1691-T-30-TGW
8:01-CV-1692-T-30-MAP
8:01-CV-1694-T-30-MAP
8:01-CV-1695-T-30-MAP
8:01-CV-1696-T-30-EAJ
8:01-CV-1702-T-30-TGW
8:01-CV-1703-T-30-EAJ
8:01-CV-1704-T-30-TGW
8:01-CV-1724-T-30-MAP

ORDER ON JURISDICTIONAL ISSUES'

This cause came on for consideration upon the Plaintiff's motion for remand (Dkt. 9), Defendant's opposition thereto (Dkts. 10, 12) and other submissions concerning this Court's subject matter jurisdiction. Specifically, Defendants requested that all cases be consolidated with the judge in the lowest numbered case for resolution of all jurisdictional matters. (Dkts. 8, 25). Pursuant to Local Rule 1.04, the Honorable Judge James S. Moody Jr. received transfer of all diet drug cases pending in the Middle District of Florida with the exception of twelve cases² pending before the Honorable James D. Whittemore.

¹ The docket numbers referred to in this Order are for Case No. 8:01-cv-1587-T-30MAP; the jurisdictional rulings herein apply to each of the cases listed above.

² Subsequently, the parties in one of these cases agreed to remand the case to state court after finding diversity of citizenship lacking. See Scharle v. American Home Products Corp., Case No. 8:01-cv-1601-T-27EAJ. Accordingly, there are 11 cases pending before Judge Whitemore.

Plaintiff filed supplemental material on the motion for remand. (Dkt. 21). Additionally, Defendant filed motions for leave to conduct discovery regarding jurisdiction. (Dkt. 20). The Court heard the arguments of counsel on October 29 and November 27, 2001, and reviewed supplemental briefs submitted by the parties on certain jurisdictional issues, as permitted by the Court. (Dkts. 26-27, 30-34, 36, 38). Upon careful consideration, the Court finds that these cases were properly removed to this Court for the reasons set forth herein.

BACKGROUND

This case and the seventy-two other product liability cases removed from the Sixth Judicial Circuit Court in and for Pinellas County, Florida, involve the prescription diet drugs, Pondimon (fenfluramine) and Redox (dexfenfluramine),² and allege personal injury damages caused from the ingestion of these drugs. These cases are currently in the process of transfer, as potential tag-along cases, to the diet drug Multi-District Litigation (MDL) pending in the Eastern District of Pennsylvania before the Honorable Louis C. Bechtle.³ See In re Diet Drugs (Phentermine / Fenfluramine / Dexfenfluramine) Products Liability Litigation, MDL Docket No. 1203, U.S. District Court, Eastern District of Pennsylvania. A conditional transfer order has been entered and Plaintiffs have filed an opposition to the transfer, at least in part based upon the pendency of the jurisdictional issues resolved herein. This Court has otherwise stayed all pretrial proceedings pending the resolution of the transfer. (Dkt. 25).

In the MDL, an "Official Court Notice of Nationwide Diet Drug Class Action Settlement" was filed. The Plaintiffs in the cases pending before this Court have opted out of this settlement;

² These diet drugs were voluntarily withdrawn from the market in September 1997.

³ These cases were initially consolidated by Order of the Judicial Panel on Federal Multi-District Litigation on December 12, 1997.

although Plaintiff filed the official settlement notice herein in support of her motion to remand this action to state court on the grounds that Defendant failed to establish that the amount in controversy is greater than the required amount of \$75,000.

After Plaintiff filed motions for remand, Defendant objected that Plaintiff's motion for remand was untimely⁴ because it was filed thirty-one days after Defendant filed its notice of removal. The time for filing a motion to remand is set in 28 U.S.C. §1447(c) which states, in pertinent part:

A motion to remand the case on the basis of any defect other than lack of subject matter jurisdiction must be made within 30 days after the filing of the notice of removal under section 1446(a).

Because Defendant brought up the issue of untimeliness at the October 29 hearing, the Court permitted Plaintiff to file a supplemental brief on this issue.

Under the removal statute, an untimely motion precludes the Court's review of defects "other than lack of subject matter jurisdiction" and acts like a waiver by Plaintiff of any procedural defects in the removal. See Brown v. Prudential Ins. Co. of America, 954 F. Supp. 1582, 1584 (S.D. Ga. 1997); see also In re Plowman, 218 B.R. 607, 613 (N.D. Al. 1998) (explaining 1996 amendment regarding defects in removal). Plaintiff's motion for remand makes two arguments for "procedural defects" in Defendant's removal: (1) the timeliness of the filing of the removal notice, and (2) Defendant's failure to obtain the consent of one of the other co-defendants prior to removal. Accordingly, the Court must first review Defendant's objection to timeliness of the motion for remand prior to addressing to the merits of the remand motion as it relates to those defects other than lack of subject matter jurisdiction.

⁴ Defendant concedes that in one of the cases, Lockhart v. American Home Products Corp., Case No. 8:01-cv-1704-T-30TGW, Plaintiff filed a timely motion for remand. This case is specifically discussed *infra*. Additionally, in five of the cases, Plaintiff failed to file a motion for remand but filed a supplement to the motion to remand. Because Plaintiff filed a supplemental brief on the issue of remand in these cases, the Court considers whether remand is appropriate for all cases.

Plaintiff's motion for remand also disputes that Defendant has established subject matter jurisdiction. First, Plaintiff asserts that because the complaint incorporates the allegations contained in a "Master Complaint" filed in the state court action, several of the defendants are not diverse in citizenship from the Plaintiff.⁵ Second, Plaintiff asserts that Defendant has not established that this case involves \$75,000 in controversy as required for this Court to have subject matter jurisdiction pursuant to 28 U.S.C. §1332.⁶ This Court permitted the parties to file additional materials concerning the amount in controversy. See Williams v. Best Buy, 269 F.3d 1316 (11th Cir. 2001).

LEGAL ANALYSIS

This Court is faced with the decision of whether Plaintiff's motion for remand, filed thirty-one days after Defendant filed its notice of removal, is untimely under the removal statute, 28 U.S.C. §1447.⁷ If found to be untimely, the Court is precluded from addressing the Plaintiff's arguments that (1) Defendant's notice of removal was filed untimely and (2) Defendant failed to obtain the consent of one of the other co-defendants. Plaintiff also raises lack of subject matter jurisdiction in the motion to remand. See Hobbs v. Blue Cross Blue Shield of Alabama, 1283650 (11th Cir. Oct. 24, 2001) (court must determine whether subject matter jurisdiction exists over a pending action "whether or not this issue was raised before"). Accordingly, the Court will first address the issue of lack of subject matter jurisdiction.

⁵ Initially, this Court *sua sponte* remanded five cases on the grounds that diversity of citizenship did not exist because Plaintiff incorporated several non-diverse defendants from the "Master Complaint" into these actions. Upon remand, Defendant again removed these cases and clarified that the many of the non-diverse defendants were *not* incorporated into this action and complete diversity existed. At the October 29 hearing, the Court ruled *ore tenus* that the incorporation of the "Master Complaint" does not defeat diversity of citizenship. See Dkt. 22.

⁶ Plaintiff concedes, in supplemental briefing (Dkt. 38, p. 2), that based on certain Plaintiffs' injuries, 18 of the cases meet the amount in controversy requirement.

⁷ There are two "batches" of cases that were removed. The first batch was removed on August 28, 2001, and the second batch was removed on September 4, 2001.

Lack of Subject Matter Jurisdiction

Plaintiff asserts that Defendant has failed to establish in its removal notice that it has met the amount in controversy requirement of \$75,000. Defendant's removal notice reads, in pertinent part, that "no verdict entered in any similar case has been for less than \$75,000. *See, e.g.,* Media Reports, attached as Exhibit C. Accordingly, on its face, Plaintiff's Complaint places more than \$75,000 in controversy." Dkt. 1, ¶11. Plaintiff's complaint alleges the amount in controversy exceeds \$15,000, as required for the state court's jurisdiction, and argues that the allegations in Defendant's removal notice fall short of the meeting the burden required of a removing party. *See Golden v. Dodge-Markham Co., Inc.*, 1 F. Supp.2d 1360 (M.D. Fla. 1998).

The Eleventh Circuit recently addressed the burden the removing party must carry in properly removing a case under the Court's diversity jurisdiction. *See Williams v. Best Buy Co.*, 2001 WL 1244759 (11th Cir. Oct. 18, 2001). When the complaint fails to seek a specified amount of damages, the removing party need only show, by a preponderance of the evidence, that the amount in controversy exceeds \$75,000. *Id.*

Defendant asserts that the allegations in Plaintiff's complaint are sufficient to establish the amount in controversy. Plaintiff alleges, in pertinent part, that she has sustained "serious and permanent injuries including, but not limited to, injuries of the heart, pulmonary system and/or neurological and other physical injuries; disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future." *See* Dkt. 1, ¶11, *citing* Plaintiff's Master Complaint. Defendant also cites to cases with similar allegations that were found to have sufficiently supported the amount in controversy requirement. Defendant further asserts, in its notice of removal, that no verdict "in a similar case" has been entered for less than \$75,000. Plaintiff

asserts that Defendant has failed to make an "affirmative showing" that Plaintiff's allegations meet this threshold requirement.

Defendant initially requested permission to conduct discovery on this issue. See Dkt. 11. The Court did not grant this request, instead permitting the parties to file additional material supporting their arguments. In these additional pleadings, Plaintiff filed the official court notice of settlement from the MDL case. See Dkt. 21. She analogizes her case to those covered by the class action settlement notice who are listed as only receiving \$6000-10,000 based on their injuries, and contends that Defendant can not affirmatively show that similar cases have damages greater than \$75,000.

Defendant, however, filed the declaration of one of the attorneys involved in the AHP litigation who cites five diet drug cases in various state courts that had jury verdicts (all of the cases reaching verdict and including only compensatory damages) ranging from \$1.75 million to \$30 million. See Dkt. 34. In the Declaration, Mr. Grossi also attests that the plaintiffs in those cases alleged similar "broadly worded" claims for damages and argued at trial that their conditions were likely to deteriorate and may require surgery in the future.

At the hearing on this issue, the Court found Defendant's supplemental filings to be compelling and informed Plaintiff's counsel that only a stipulation by Plaintiff that she was not seeking in excess of \$75,000 would overcome the declaration filed by Defendant. Plaintiff declines to so stipulate. In the absence of such a stipulation, the Court finds that Defendant has met its burden under the law of this Circuit and established the amount in controversy requirement pursuant to 28 U.S.C. §1332.

Timeliness of Plaintiff's Motion for Remand

Defendant asserts that Plaintiff's motion for remand is untimely because she failed to file her motion within thirty-days of the filing of Defendant's notice of removal. This issue must be addressed before the Court looks to the two "procedural defect" grounds raised by Plaintiff in the motion for remand. If the motion for remand is untimely, these Court will not address the merits of these defects because Plaintiff is deemed to have waived any objections to procedural defects in the removal. Defendant's removal will not be disturbed once subject matter jurisdiction has been established.

Defendant contends that this issue is controlled by the plain words of the removal statute, Plaintiff has thirty days from the filing of the notice of removal to file a motion for remand "on the basis of any defect other than lack of subject matter jurisdiction." Failure to do so bars the raising of any "procedural" or "technical" defects with the removal. Plaintiff contends that he should be permitted the additional three days for mail time afforded by Fed. R. Civ. P. 6(e). Rule 6(e) reads in pertinent part;

Whenever a party has the right or is required to do some act or take some proceedings within a prescribed period after the service of a notice or other paper upon the party and the notice or paper is served upon the party by mail, 3 days shall be added to the prescribed period.

The only federal appellate court to squarely address this issue has clearly held that the plain words of the statute control and the mail time set forth in Rule 6(e) does not extend the thirty-day time period to file a motion for remand, "as that rule only applies when a party is required to act within a prescribed period after *service*, not after *filing*." Pavone v. Mississippi Riverboat Amusement Corp., 52 F.3d 560, 566 (5th Cir. 1995). See also In re: Bethesda Memorial Hosp., 123 F.3d 1407, 1410-11 (11th Cir. 1997) (in determining that remand order was reviewable when case was remanded on procedural defect after 30 days of removal notice, court looked to "plain language"

of 28 U.S.C. §1447(c) and finds it was "bound by the thirty-day limit"); Clements v. Florida East Coast Ry. Co., 473 F.2d 668, 670 (5th Cir. 1973)⁸ ("Rule 6(e) has no application [when] the action required of plaintiff was not within a prescribed period after service of the order upon him.").

Plaintiff responds by looking at several district court opinions that have specifically permitted a plaintiff to add the three-day mail time from Rule 6(e) to motions for remand when the defendant served the removal notice by mail. See McPherson v. Peele Co., 1995 WL 56600 (E.D. Pa. 1995); McGovern v. Mucklow, 1992 WL 160639 (E.D. Pa. 1992); Chott v. Cal Gas Corp., 746 F. Supp. 1377 (E.D. Mo. 1990); but see Lewis v. Certainteen Corp., 870 F. Supp. 130 (W.D. La. 1994) (not allowing Rule 6(e) mail time for motion to remand). Plaintiff urges the Court to rule as did the two Eastern District of Pennsylvania cases that allowed Rule 6(e) mail time for motions to remand, pointing to the equity of utilizing the law of the district in which the MDL is pending. But see Robinson v. Nutter, 1995 WL 61158, *4, n.4 (E.D. Pa. 1995) (plaintiffs are not permitted to "avail themselves of the three-day grace period provided in [] Rule 6(e)" for filing their motion to remand); cf. Mosel v. Hills Department Store, 789 F.2d 251 (3d Cir. 1986) (mail time did not apply to extend 90-day period following receipt of right-to-sue letter from Equal Employment Opportunity Commission within which employee was required to file employment discrimination complaint -- Rule 6(e) only applies "where a time period is measured from the date of service by mail").

As the Court noted at the hearing on this matter, were it to rule on the issue "from scratch," it would rule the way the court did in the footnote four in the Robinson case because the period for filing a motion to remand is commenced by *filing*, not by *service*. However, at the hearing, the Court also noted the unfairness of applying law to this case contrary to the law found in the two Eastern

⁸ Fifth Circuit decisions handed down prior to October 1, 1981, are binding precedent upon this Court. Bonner v. City of Pritchard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc).

District of Pennsylvania courts cited by Plaintiff because that is where the diet drug MDL action is pending and where these cases are likely to be transferred if they remain in federal court. These two cases specifically permitted an extra three days mail time for motions to remand so that motions filed thirty-three days after the removal notice was filed, if it was served by mail, would be considered timely. See McPherson v. Peele Co., 1995 WL 56600 (E.D. Pa. 1995); McGovern v. Mucklow, 1992 WL 160639 (E.D. Pa. 1992). Despite the Court's equitable leaning towards finding the motion for remand timely (by allowing the three days mail time in Rule 6(e)), upon further consideration the Court has determined that it is constrained by the plain words of the removal statute, and the Pavone, Mosel, Clements, and Bethesda Memorial Hospital cases, to find that Rule 6(e) does not extend the time period for filing a motion to remand. Accordingly, the Plaintiff's motion for remand is untimely and the Court makes no finding on the procedural defects raised by Plaintiff for the cases in which the motion for remand was filed thirty-one days after the removal notice was filed.

Case No. 8:01-cv-1704-T-30TGW

To conserve judicial resources and paper, the Court directed the parties to file all pleadings in this lowest numbered case, Delonne v. American Home Products Corp., Case No. 8:01-cv-1587-T-30MAP, while reviewing jurisdictional issues. See Dkt. 23. In Defendant's supplemental brief on jurisdiction, Plaintiff attached a table listing the time period in which the motions for remand were filed in each removed diet drug case. See Dkt. 27, Exh. A. There was only one case in which the motion for remand was timely filed -- Lockhart v. American Home Products Corp., Case No. 8:01-cv-1704-T-30TGW. In this case, Plaintiff filed his motion for remand twenty-four days after

the notice of removal was filed. Accordingly, this motion is timely and the Court will address the issues raised by Plaintiff in its timely motion for remand filed in Lockhart.⁹

In this case, it is alleged that the Plaintiff, Janet Lockhart, is a resident of Orange County, Florida. Defendant American Home Products Corporation ("AHP") is a Delaware corporation with its principal place of business in New Jersey and Defendant Eon Labs Manufacturing, Inc. ("Eon Labs") is also a Delaware corporation with its principal place of business in New York. Plaintiff also named another Florida citizen, Goldline Laboratories, Inc., as a Defendant in this case. Accordingly, at that time, diversity of citizenship did not exist.

On August 3, 2001, however, Plaintiff voluntarily dismissed Goldline from the case. The notice of dismissal would be considered the first paper "from which it may first be ascertained that the case is one which is or has become removable" under 28 U.S.C. 1446(b), and upon Defendant's receipt thereof, complete diversity existed. Accordingly, Defendant timely filed for removal on September 4, 2001, invoking the Court's diversity jurisdiction pursuant to 28 U.S.C. §1332.¹⁰

Having established that the notice of removal was timely filed and that the complete diversity of citizenship existed, and establishing supra that Defendant met its burden of establishing the amount in controversy, the Court turns to the issue of whether Defendant American Home Products needed to obtain the consent of Eon Labs prior to removal. Section 1446(a) has been consistently interpreted to include a "unanimity requirement" which requires the consent to removal of all

⁹ Because Plaintiff had filed a timely motion for remand in one case and in part, due to the Court's leaning towards the equities of permitting additional mail time for Plaintiff's motion for remand, the Court heard the arguments of counsel and was fully briefed on these issues at the November 27 hearing.

¹⁰ Although this case was initially remanded *sua sponte* by this Court, Defendant's second removal notice (clarifying the grounds for removal so that the initial ground for the Court's *sua sponte* remand was no longer valid) was timely filed under 28 U.S.C. §1446(b), Fed R. Civ. P. 6(a) and Local Rule 4.20.

defendants in a case involving multiple defendants. See Russell Corp. v. American Home Assur. Co., 264 F.3d 1040, 1044 (11th Cir. 2001) ("the unanimity requirement mandates that in cases involving multiple defendants, all defendants must consent to removal"). Of course, if Eon Labs was not served at the time AHP removed this case, as AHP contends, Eon Labs' consent was not required.

Plaintiff offers as evidence that Eon Labs was served, a letter from its counsel dated September 25, 2001, agreeing that prior delivery of the complaints by mail on local counsel constituted service. See Dkt. 9, Exh. 3. Defendant submitted affidavits of counsel that prior to removing this case to federal court, counsel contacted counsel for Eon Labs to confirm that Eon Labs had not been served. See Dkt. 10, Exh. A. Defendant argues that because Eon Labs and Plaintiff's counsel came to an agreement *after* the date of removal, they should not be precluded from removing the case because there is no way that Defendant AHP could have known service would later be attained on a date prior to their removal.¹¹

The Court is persuaded by Defendant's arguments. As the Court ruled *ore tenus* at the hearing, Defendant met their burden in filing their notice of removal on this issue. Defendant exhibited diligence in checking the state court file and calling Eon Labs' counsel to confirm whether service had occurred prior to removal, presumably knowing that if Eon Labs had been served they would have to obtain their consent prior to removal.¹² Plaintiff's counsel counters that defense

¹¹ Counsel for Defendant AHP also attests that he checked the state court docket to determine if service of process on Eon Labs had been attained. See Dkt. 10, Exh. A.

¹² A fact which was not likely to occur. Defendant notes, in the affidavit of counsel, that Eon Labs previously agreed with Plaintiff, as they had done in other similar cases, not to consent to removal. Nonetheless, counsel for Eon Labs did confirm to AHP's counsel when contacted prior to filing the notice of removal, that to his knowledge Eon Labs had not been served with process. See Dkt. 10, Exh. A.

counsel should have checked with Plaintiff's counsel. The Court does not find this argument countervailing in these circumstances. Plaintiff's motion for remand in this case is also denied.

It is thereby **ORDERED** and **ADJUDGED** that Plaintiff's Motion for Remand (Dkt. 9) is denied as set forth herein and those diet drug cases removed from the Sixth Judicial Circuit Court in and for Pinellas County are hereby found to have been properly removed to this Court. Defendant's Motion to Conduct Discovery Regarding Jurisdiction (Dkt. 11) and Plaintiff's Motion to Transfer Cases and for Protective Order (Dkt. 35) are therefore denied as moot.

DONE and **ORDERED** in Tampa, Florida on this 4 day of December, 2001.



JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record

EXHIBIT 4

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

**NOTICE OF FILING
NOTICE OF REMOVAL**

Index No.: 07/114306

Plaintiff,

-against-

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC CORPORATION,
MICHAEL LIOU, M.D., BETH ISRAEL MEDICAL
CENTER AND BETH ISRAEL MEDICAL CENTER
PHILIPS AMBULATORY CARE CENTER

Defendants.
-----X

TO: THE CLERK OF THE SUPREME COURT OF THE STATE OF NEW YORK

You are hereby notified that Defendants Guidant Corporation ("Guidant"), Guidant Sales Corporation ("GSC") and Boston Scientific Corporation ("BSC") and have on this 20th day of November, 2007, filed in the United States District Court for the Southern District of New York, a Notice of Removal to Federal Court of the above-entitled cause, a copy of which is attached hereto and made a part of the Notice to Clerk, for your information and guidance. This Notice serves to effect full removal of this case pursuant to 28 U.S.C. § 1446(d), thereby precluding this State Court from proceeding further in this case, unless and until this case is remanded hereto by the United States District Court.

Dated: November 20, 2007

Respectfully submitted,

By: _____
Kimberly S. Penner
kpenner@mccarter.com
McCARTER & ENGLISH, LLP
245 Park Avenue, 27th Floor
New York, New York 10167-0001
212-609-6800

and

SHOOK, HARDY & BACON, L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108
816-474-6550

Attorneys for Defendants
Guidant Corporation,
Guidant Sales Corporation and
Boston Scientific Corporation

EXHIBIT 5

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: GUIDANT CORP. IMPLANTABLE
DEFIBRILLATORS PRODUCTS
LIABILITY LITIGATION

MDL No. 05-1708 (DWF/AJB)

This Document Relates to:

Emmett David Brown,

Plaintiff,

v. Civil No. 07-1487 (DWF/AJB)

Guidant Corporation, an Indiana Corporation;
Endovascular Technologies, Inc., a California
Corporation and a Division of Guidant
Corporation; Guidant Sales Corporation; and
Dr. Leland B. Housman,

Defendants.

**MEMORANDUM
OPINION AND ORDER**

Jeanette Haggas, Esq., Mark E. Burton, Jr., Esq., Nancy Hersh, Esq., and Rachel Abrams, Esq., Hersh & Hersh, counsel for Plaintiff.

Timothy A. Pratt, Esq., Sara J. Romano, Esq., and Dana N. Gwaltney, Esq., Shook Hardy & Bacon, LLP, counsel for Defendants Guidant Corporation, Endovascular Technologies, Inc., and Guidant Sales Corporation.

Michael I. Neil, Esq., and David P. Burke, Esq., Neil, Dymott, Frank, Harrison & McFall, APLC; and Timothy A. Pratt, Esq., Shook Hardy & Bacon, LLP, counsel for Defendant Dr. Leland B. Housman.

The above-entitled matter is before the Court pursuant to Plaintiff Emmett David Brown's Motion to Remand and Motion for Sanctions [28 U.S.C. § 1447] (MDL

No. 05-1708 (DWF/AJB), Doc. No. 1896; Civ. No. 07-1487 (DWF/AJB), Doc. No. 13) and Defendant Leland Housman, M.D.'s Motion to Sever Medical Malpractice Action and Remand Case Back to Superior Court, State of California, County of Santa Clara (MDL No. 05-1708 (DWF/AJB), Doc. No. 1801; Civ. No. 07-1487 (DWF/AJB), Doc. No. 7). For the reasons stated below, the Court grants Brown's Motion to Remand as to Dr. Housman but denies the Motion as to all remaining Defendants, denies Brown's Motion for Sanctions, and grants Dr. Housman's Motion to Sever and Remand.

BACKGROUND

In 2003, Dr. Housman implanted a Guidant defibrillator in Brown. In June 2005, Brown's defibrillator was recalled. Thereafter, Dr. Housman explanted and replaced Brown's defibrillator and epicardial leads. After the explant and replacement surgery, the leads penetrated through the surgery incision sites on Brown's chest. This penetration caused infection and the need for further surgeries.

On October 24, 2006, Brown filed this case against Defendants Guidant Corporation, Guidant Sales Corporation, Endovascular Technologies, Inc. ("EVT"),¹ and Dr. Housman in the California Superior Court of Santa Clara County, California. Guidant Corporation and Guidant Sales Corporation (collectively "Guidant") are citizens of Indiana. It is undisputed that Brown and Dr. Housman are California residents. The parties dispute EVT's citizenship. Brown asserts that EVT is a citizen of California, and Guidant and EVT assert that EVT is a citizen of Minnesota and Delaware.

¹ EVT is a wholly owned subsidiary of Guidant Corporation.

Brown alleges that Dr. Housman committed medical negligence because he implanted a defective defibrillator and negligently removed and replaced it. Brown also asserts that Dr. Housman knew of information provided by Guidant and/or EVT regarding defects with the defibrillators. Brown alleges that Guidant breached its duties as a manufacturer, distributor, and marketer of defibrillators. As to EVT, Brown alleges that it breached its reporting duties under a Corporate Integrity Agreement.

On January 22, 2007, Guidant and EVT removed the case to the United States District Court for the Northern District of California based on diversity of citizenship, asserting that EVT and Dr. Housman were improperly joined. Thereafter, Guidant sought to transfer the case, and on March 6, 2007, the Judicial Panel on Multidistrict Litigation transferred the action to the District of Minnesota as part of MDL No. 1708. On May 18, 2007, Defendant Dr. Housman filed a Motion to Sever and Remand the allegations against him, and, on June 5, 2007, Brown filed a Motion to Remand and Motion for Sanctions.

I. Motion to Sever and Remand

Dr. Housman asserts that Brown misjoined Dr. Housman as a party and that the claims against him should be severed from the claims asserted against Guidant and EVT and remanded to state court. The Federal Rules of Civil Procedure allow for permissive joinder of defendants as follows:

All persons . . . may be joined in one action as defendants if there is asserted against them jointly, severally, or in the alternative, any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action.

Fed. R. Civ. P. 20(b).² If defendants have been misjoined for the failure to satisfy the conditions for permissive joinder under Rule 20(b), the Rules allow for severance of those defendants:

Misjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just. Any claim against a party may be severed and proceeded with separately.

Fed. R. Civ. P. 21.

Dr. Housman asserts that the claims against him (medical negligence) and Guidant (product liability) are legally distinct and that none of the causes of action overlap one another. In addition, Dr. Housman asserts that the facts that would support a claim against him involve the quality of medical care given to Brown, whereby the facts that would support a claim against Guidant would have nothing to do with the standard of care for Dr. Housman, but instead would focus on the products used. Therefore, Dr. Housman contends that the claims arising out of his treatment do not arise out the same transaction or occurrence as the claims against Guidant and EVT.³

Brown, on the other hand, contends that Dr. Housman, Guidant, and EVT's actions/inactions do arise out of the same transaction or occurrence. Brown asserts that

² The California rule on permissive joinder is nearly identical to the federal rule and is identical in all relevant parts here. See Cal. Civ. Proc. Code § 379(a)(1).

³ To the extent that the Court finds that severance and remand is necessary, Guidant and EVT agree with Dr. Housman to the extent that only Dr. Housman should be severed and remanded and that the Court should retain jurisdiction over Brown's claims against Guidant and EVT.

he would not have had to endure the surgery whereby the leads were misplaced if his Guidant defibrillator was not defective. Brown also asserts that his surgery shares common questions of law and/or fact with Brown's product liability claims against Guidant and EVT. Brown contends that the chain of events that led to Brown's injury inextricably connects the facts and legal issues surrounding the medical negligence and product liability claims. Specifically, Brown asserts that Dr. Housman's testimony, notes, and other related information regarding Brown's implant and explant surgeries will be required for the negligence, fraud, and CLRA claims against Guidant. Further, Brown contends that he makes the same claim for damages against all Defendants and that each Defendant is jointly and severally liable for the damages Brown sustained.

Upon review of the applicable rules and the pleadings of the parties, the Court finds that Dr. Housman has been improperly joined in this case. Brown's claim against Dr. Housman is medical negligence, which would require evidence on Brown's care, treatment, and services provided by Dr. Housman. Brown's claims against either Guidant or EVT are general negligence or product liability claims based on alleged manufacturing and design defects, alleged failure to properly warn, and alleged misrepresentation of the health risks associated with certain cardiac medical devices. These claims would require evidence on the development, manufacture, and testing of Brown's ICD along with evidence of Guidant and EVT's knowledge, warnings, and representations regarding defective ICD's. The joinder of the malpractice claim against Dr. Housman with the other general negligence and product liability claims was inappropriate because the claims do not both involve common questions of law or fact

and assert joint, several, or alternative liability “arising out of the same transaction, occurrence, or series of transactions or occurrences.” Fed. R. Civ. P. 20(b). Any liability that may be found against either Guidant/EVT or Dr. Housman would not be a basis for liability as to the other. However, separate liability as to each could be separately found.⁴ Furthermore, because of the nature, stage, and progression of this MDL, especially in light of the proposed settlement involving Guidant, “the rights of the parties and interest of justice is best served by severance.” Fed. R. Civ. P. 21.

Although some courts faced with fraudulent misjoinder claims have required both a finding of misjoinder and a finding of a bad faith attempt to defeat diversity, other courts have refused to apply the “egregious” standard when considering misjoinder in the context of remand petitions. *See In re: Baycol Products Litig.*, MDL No. 1431 (MJD), Case. No. 03-2931, 2003 WL 22341303, at *3 (D. Minn. 2003) (citing cases). The Eighth Circuit Court of Appeals has not addressed the issue.

Here, as the court in *Greene v. Wyeth* found, the Court “rejects the notion that Plaintiff[] ha[s] committed an egregious act or fraud upon the Court.” 344 F. Supp. 2d

⁴ While California case law seems to take a broad view of joinder, the Court’s finding is still consistent. The California Supreme Court has stated that section 379, subdivision (c) “does not permit the unlimited joinder of defendants; it provides for joinder only when plaintiff pleads a specific relationship between the defendants, namely, a single or cumulative injury, giving rise to doubt as to the respective liability of defendants for that injury. In other words, when a plaintiff states facts showing a reasonable uncertainty as to the respective liability of the defendants, these same facts constitute the connection that links the acts of the defendants and fulfills any claimed requisite of ‘factual nexus.’” *Landau v. Salam*, 484 P.2d 1390, 1395 (Cal. 1971). Here, Brown has not alleged that he is in doubt as to which Defendant is liable for which actions.

674, 685 (D. Nev. 2004). “[U]nder our dual court system[, if] a potential plaintiff has a choice between a state forum and a federal forum, it is his privilege to exercise that choice subject to legal limitations, and if he can avoid the federal forum by the device of *properly* joining a non[-]diverse defendant or a non[-]diverse co-plaintiff, he is free to do so.” *Iowa Pub. Serv. Co. v. Med. Bow Coal Co.*, 556 F.2d 400, 406 (8th Cir. 1977) (emphasis added). However, where a non-diverse party, such as Dr. Housman here, cannot be properly joined under the Federal Rules of Civil Procedure, other interests, such as the Defendants’ statutory right of removal, prevail over that of permitting a plaintiff’s choice of forum. *See Greene*, 344 F. Supp. 2d. at 685. Because the basis for the causes of action against Dr. Housman do not arise from the same transaction and occurrences as those in the causes of action against Guidant and EVT, the Court will sever the action against Dr. Housman so as to preserve Guidant and EVT’s right to removal in the remaining action and to preserve the interests of judicial expediency and justice.

II. Motion to Remand

The party seeking removal and opposing remand bears the burden of establishing federal subject matter jurisdiction. *In re Bus. Men’s Assurance Co. of Am.*, 992 F.2d 181, 183 (8th Cir. 1993). Generally, a state court action may only be removed if a federal district court would have original jurisdiction to hear the case. 28 U.S.C. § 1441(a).⁵

⁵ Section 1441(a) provides in pertinent part:

(Footnote Continued on Next Page)

Where the action is based upon diversity jurisdiction, it is removable “only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.” 28 U.S.C. § 1441(b). A corporation is deemed a citizen of the state in which it is incorporated and of the state where it has its principal place of business. 28 U.S.C. § 1332(c)(1). “In determining whether removal was proper, the removal statute is to be narrowly construed and all doubts about the propriety of federal jurisdiction are to be resolved against removal.” *In re Potash Antitrust Litig.*, 866 F. Supp. 406, 410 (D. Minn. 1994). “If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded.” 28 U.S.C. § 1447(c).

Brown argues that the Court should remand the entire action asserting lack of subject matter jurisdiction and defects in the removal procedure. As to the latter, Brown contends that Guidant and EVT’s removal was untimely, did not have proper consent from Dr. Housman, was facially deficient, and did not meet the requisite amount in controversy.

(Footnote Continued From Previous Page)

[A]ny civil action brought in a state court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or defendants, to the district court of the United States.

28 U.S.C. § 1441(a).

A. Timeliness/Consent/Deficiency

Brown served Dr. Housman on December 14, 2006. Guidant and EVT removed the action on January 22, 2007. Brown argues that Guidant and EVT had no right to remove because Dr. Housman did not remove nor consent to removal within thirty days of service of the Complaint. Brown also argues that Guidant's removal is facially deficient because Guidant did not explain why Dr. Housman had not joined in the removal. Guidant and EVT assert that Guidant's removal was proper and timely because all properly-joined Defendants consented to removal and neither Guidant nor EVT were served with a summons and complaint; therefore, the 30-day period for removal was never triggered.

"The notice of removal of a civil action . . . shall be filed within thirty days after the receipt by the defendant, through service or otherwise, of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based." 28 U.S.C. § 1446(b); *see also* *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 348 (1999) (holding that a defendant's time to remove is triggered by formal service of the summons and the complaint, not "by mere receipt of the complaint unattended by any formal service"). Removal is proper "if none of the parties in interest *properly joined* and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b) (emphasis added). Consistent therewith, the usual rule that all defendants in an action in state court join in a petition for removal does not apply to "nominal, unknown, or fraudulently-joined parties." *United Computer Sys., Inc. v. AT&T Corp.*, 298 F.3d 756, 762 (9th Cir. 2002).

Here, because Dr. Housman was not properly joined, his consent was neither necessary nor did the service of process on him trigger the deadline for removal. Further, as to Brown's assertion that Guidant's removal was facially deficient, the Court disagrees. Guidant and EVT stated in their Notice of Removal that Dr. Housman was improperly joined. (Aff. of Timothy A. Pratt in Supp. of Defs. Guidant Corporation, Endovascular Technologies, Inc. and Guidant Sales Corporation's Opp'n to Pl.'s Mot. to Remand ("Pratt Aff."), Ex. A at 3.) Guidant and EVT also stated that all properly-joined Defendants had consented to removal and that Defendants who are not properly joined need not consent to removal. (*Id.*) Therefore, the Notice of Removal was not facially deficient because Guidant did explain why it did not have Dr. Housman join in the removal. Thus, Brown's untimeliness, non-consent, and facially deficient arguments fail.

B. Requisite Amount in Controversy

Brown also asserts that Guidant and EVT have failed to show the action meets the requisite amount in controversy. Brown points to Guidant and EVT's Notice of Removal, whereby Guidant and EVT assert that the "face of the complaint makes clear that plaintiff seeks damages in excess of \$75,000" because Brown seeks "damages for surgical placement and replacement of an allegedly defective defibrillator in him." (Pratt Aff., Ex. A at 11.) Brown contends that this is insufficient to demonstrate that the amount in controversy exceeds \$75,000. Guidant and EVT, on the other hand, assert that they have met their burden. Guidant and EVT point to Brown's allegations in the Complaint where he alleges "serious injuries to his chest," (Compl. ¶ 130), and alleges that he "required healthcare and medical services, and incurred direct medical costs for

physician care, monitoring, treatment, medications, and supplies.” (*Id.*) Guidant and EVT also point out that Brown is seeking general, special, and punitive damages, restitution and disgorgement of profits, compensatory and other damages, costs, including experts’ fees and attorneys’ fees and expenses, and the costs of prosecuting this action. (Compl., Prayer for Relief at 24.) The Court finds that in light of the allegations plead and in light of the other complaints filed by Brown’s attorneys directly in this MDL alleging similar claims and damages whereby they plead that the requisite jurisdictional amount was met, a jury could return an award in excess of \$75,000. Therefore, Brown’s argument fails.

C. Subject Matter Jurisdiction

Brown contends that the Court lacks subject matter jurisdiction, asserting that removal was improper under 28 U.S.C. § 1441(a) because Dr. Housman and EVT are California residents, thereby creating incomplete diversity of citizenship. As to EVT, Brown contends that Guidant has admitted in Answers that it has filed that EVT maintains its principal place of business in California. Therefore, Brown asserts that EVT is a citizen of California causing the Court to have no original jurisdiction. Brown also asserts that under 28 U.S.C. § 1447(c), the case must therefore be remanded.

Guidant and EVT assert that complete diversity of citizenship does exist. Guidant and EVT contend that Dr. Housman’s citizenship should be disregarded because he was improperly joined as a defendant. The Court agrees, as is explained above.

As to EVT’s citizenship, Guidant and EVT assert that EVT is not a California citizen. Guidant points out that the pleadings that Brown sites to for support that EVT is

a California citizen date back to 2002 and 2003. Guidant explains that at that time, EVT's principal place of business was in California. But Guidant asserts that in October 2006, when the Complaint was filed here, and in January 2007, when the case was removed, EVT had no business operations in California. Citing to Jeffrey Kruse's declaration, Senior Counsel for EVT, Guidant asserts that since June 30, 1989, EVT has been a Delaware corporation, and since April 2006, EVT has had its headquarters and business operations in St. Paul, Minnesota. Therefore, Guidant and EVT assert that EVT is a citizen of Delaware and Minnesota.

Brown's only response to Guidant's assertion is that EVT was a California citizen at the time he was injured in March 2004. Brown, however, asserts no authority for the proposition that the Court should analyze citizenship as of the date of injury for purposes of diversity jurisdiction.

The Court agrees with Guidant and EVT that EVT is not a California citizen. For purposes of diversity jurisdiction, the Court analyzes citizenship as of the date that the Complaint was filed. *Grupo Dataflux v. Atlas Global Group, LP*, 541 U.S. 567, 571 (2004). Therefore, because at the time that the Complaint was filed, EVT was a citizen of Delaware and Minnesota, Guidant was a citizen of Indiana, and Brown was a citizen of California, complete diversity of the parties exists,⁶ and the Court denies Brown's

⁶ The Court disregards Dr. Housman's citizenship because he was improperly joined in this case, as is explained above.

Motion to Remand as to his case against Guidant and EVT.⁷ Consistent with the Court granting Dr. Housman's Motion to Sever and Remand, the Court grants in part Brown's Motion to Remand only to the extent that the Court severs and remands Brown's claims against Dr. Housman.

II. Motion for Sanctions

Based on Brown's assertion that the parties here are properly joined and non-diverse and because Dr. Housman did not consent to removal, Brown also contends that Guidant should be sanctioned for removing this action. Here, because the Court finds that Guidant and EVT's removal was proper and because the record does not show bad faith on the part of Guidant or EVT, the Court concludes that sanctions are not warranted.

IT IS HEREBY ORDERED that:

1. Defendant Leland Housman, M.D.'s Motion to Sever Medical Malpractice Action and Remand Case Back to Superior Court, State of California, County of Santa Clara (MDL No. 05-1708 (DWF/AJB), Doc. No. 1801; Civ. No. 07-1487

⁷ Guidant and EVT argued alternatively that if the Court found EVT to be a citizen of California, that EVT's citizenship should be disregarded because it was fraudulently joined as a defendant. Because the Court finds EVT to be a California citizen, it need not address whether EVT was fraudulently joined. However, "[j]oinder is fraudulent only where there is no reasonable basis in fact or colorable ground supporting the claim against the resident defendant, or where the plaintiff has no real intention of prosecuting the action against the resident defendant." *Schwenn v. Sears, Roebuck & Co.*, 822 F. Supp. 1453, 1455 (D. Minn. 1993). And, because "contested issues of fact should be resolved in favor of the plaintiff," *id.*, the Court notes that, at this juncture, fact issues would preclude the Court from finding that there is no basis for liability.

(DWF/AJB), Doc. No. 7) is **GRANTED**. The Court Orders that all claims against Defendant Leland Housman, M.D. are **SEVERED** and **REMANDED** to Superior Court, State of California, County of Santa Clara.

2. Plaintiff Emmett David Brown's Motion to Remand and Motion for Sanctions [28 U.S.C. § 1447] (MDL No. 05-1708 (DWF/AJB), Doc. No. 1896; Civ. No. 07-1487 (DWF/AJB), Doc. No. 13) is **GRANTED** as to the remand of Defendant Leland Housman, M.D., but **DENIED** as to the remand of all remaining Defendants and **DENIED** as to Brown's Motion for Sanctions.

Dated: August 30, 2007

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court

EXHIBIT 6

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**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

**In re: GUIDANT CORP. IMPLANTABLE
DEFIBRILLATORS PRODUCTS
LIABILITY LITIGATION**

MDL No. 05-1708 (DWF/AJB)

This Document Relates to:

Donald Alexander,

Plaintiff,

v. Civil No. 07-1129 (DWF/AJB)

**Boston Scientific Corporation, Guidant
Subsidiary of Boston Scientific Corporation,
and St. Anthony's Medical Center,**

Defendants.

**MEMORANDUM
OPINION AND ORDER**

Donald Alexander, 31057 Oak Ridge Drive, Rocky Mount, MO 65072, *pro se*.

**Timothy A. Pratt, Esq., Deborah A. Moeller, Esq., and Julie R. Somora, Esq., Shook
Hardy & Bacon, LLP, counsel for Defendants Boston Scientific Corporation and Guidant
Subsidiary of Boston Scientific Corporation.**

**Douglas Ponder, Esq., Karen C. Moske, Esq., and V. Scott Williams, Esq., Hazelwood &
Weber, LLC, counsel for Defendant St. Anthony's Medical Center.**

**The above-entitled matter is before the Court pursuant to Plaintiff Donald
Alexander's Motion for Remand to St. Louis County Circuit Court and Defendant
St. Anthony's Medical Center's ("St. Anthony's") Motion to Dismiss. For the reasons
stated below, the Court grants Alexander's Motion for Remand as to Defendant**

St. Anthony's, but denies the motion as to all remaining Defendants. The Court denies St. Anthony's Motion to Dismiss as moot.

BACKGROUND

On May 25, 2006, Alexander was implanted with a Model 1291 Guidant pacemaker at St. Anthony's facilities. Alexander alleges that some of St. Anthony's nurses and staff assisted in the implant. Alexander also alleges that St. Anthony's paid for the pacemaker and included the charges for the pacemaker in Alexander's patient billing.

The Model 1291 device that was implanted in Alexander was manufactured in December 2005. Prior to its manufacture, on September 22, 2005, Guidant issued a recall regarding its Model 1291 Guidant pacemakers, among others. The recall was based on two failure modes.

As to the first failure mode, Guidant recommended that physicians "consider the projected low and declining failure rate in addition to the unique needs of individual patients in their medical decisions regarding patient management" and recommended "normal monitoring, as per device labeling." (Aff. of V. Scott Williams in Supp. of Def. St. Anthony's Mot. to Dismiss and Mem. of Law in Opp'n to Pl.'s Mot. for Remand ("Williams Aff.") at Ex. C.) In addition, Guidant stated, "As always, advise patients to seek attention immediately if they experience syncope or lightheadedness." (*Id.*) As to the second failure mode, Guidant recommended the following:

Guidant recommends verifying pacemaker operation in the packaging prior to the implant procedure. Devices exhibiting intermittent or permanent loss of output or telemetry should not be implanted.

Physicians should consider both the very low occurrence rate and that no failures have been observed after successful confirmation of pacing at implant, in addition to the unique needs of individual patients, in their medical decisions regarding patient management.

(Williams Aff. at Ex. C.)

Approximately two months later, on December 12, 2005, Guidant issued an "Advisory Update" that addressed the September 22, 2005 recall letter. There, Guidant explained the following:

In March of 2004, Guidant discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to "Failure Mode 1."

Guidant has recently discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to "Failure Mode 2." While Guidant recommends normal monitoring for patients implanted with these devices, Guidant representatives will retrieve and replace remaining hospital inventory with product free from susceptibility to "Mode 2" peri-implant failure.

INSIGNIA and NEXUS devices currently being distributed by Guidant are not subject to either failure mode and therefore are not included in either recall.

(Williams Aff. at Ex. D.) Although Alexander's Model 1291 device was manufactured in December 2005, it is unclear whether the device was manufactured and shipped prior to this December 12, 2005 Advisory Update.

Approximately one month after Alexander's implant surgery, on June 23, 2006, Guidant issued a separate recall of the Model 1291. Thereafter, on July 7, 2006, Alexander received notice from the St. Louis Metro Heart Group that the specific Guidant pacemaker that was implanted in him had been recalled in connection with defective product concerns.

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On July 25, 2006, Alexander filed this case against Defendants Boston Scientific Corporation ("BSC"), Guidant Subsidiary of Boston Scientific Corporation ("Guidant"), and St. Anthony's in the Circuit Court of St. Louis County, Missouri. It is undisputed that Alexander and St. Anthony's are both Missouri residents. Guidant is a citizen of Indiana and BSC is a citizen of Delaware and Massachusetts.

Alexander alleges that BSC and Guidant are liable for manufacturing and design defects and for the failure to warn patients of the alleged health risks and/or defects associated with certain Guidant implantable cardiac medical devices. Alexander alleges that St. Anthony's committed medical negligence because it knew or had reason to know that Alexander's Guidant device was potentially defective and because it did not advise Alexander or put Alexander on notice of these facts prior to implantation.

More specifically, Alexander alleges that:

[p]rior to the actual implant surgery, both Guidant Corporation's said and physically present employee/agent and St. Anthony's Medical Center nursing staff or a designated St. Anthony's Medical Center employee/agent had the duty to disclose to Plaintiff that the Guidant pacemaker to be implanted in Plaintiff's chest is potentially defective and that a recall had been issued for Guidant pacemakers, model 1291 in September 2005 and that there existed a known manufacturing/assembly defect such that some unspecified percentage of Guidant pacemakers, model 1291, are known to be dangerously defective.

4. Both Guidant Corporation's said employee/agent and St. Anthony's Medical Center's staff employees attending to Plaintiff on May 25, 2006 breached the duty to disclose to Plaintiff that some unspecified percentage of Guidant pacemakers, model 1291, are know[n] to be dangerously defective, that several persons have died in connection with Guidant pacemakers, and that hundreds of product liability law suits are pending against Guidant Corporation.

(Williams Aff., Ex. B at 3-4.)

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On August 25, 2006, BSC and Guidant removed the case to the United States District Court for the Eastern District of Missouri, Eastern Division, asserting that complete diversity exists because Alexander improperly joined St. Anthony's to defeat diversity jurisdiction. BSC and Guidant then filed a motion to stay all proceedings pending transfer of Alexander's case to the District of Minnesota as part of MDL No. 1708. The United States District Court for the Eastern District of Missouri granted the motion to stay and on February 7, 2007, the case was formally transferred to the District of Minnesota as part of MDL No. 1708.

On February 20, 2007, Alexander filed a Motion to Remand to St. Louis County Circuit Court, claiming that St. Anthony's is a proper defendant in the case and therefore complete diversity is lacking. On March 9, 2007, St. Anthony's filed a Motion to Dismiss, claiming that Alexander has failed to state a claim against St. Anthony's.

I. Motion to Remand

The party seeking removal and opposing remand bears the burden of establishing federal subject matter jurisdiction. *In re Bus. Men's Assurance Co. of Am.*, 992 F.2d 181, 183 (8th Cir. 1993). Generally, a state court action may only be removed if a federal district court would have original jurisdiction to hear the case. 28 U.S.C. § 1441(a).¹

¹ Section 1441(a) provides in pertinent part:

[A]ny civil action brought in a state court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or defendants, to the district court of the United States.

28 U.S.C. § 1441(a).

Where the action is based upon diversity jurisdiction, it is removable “only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.” 28 U.S.C. § 1441(b). “In determining whether removal was proper, the removal statute is to be narrowly construed and all doubts about the propriety of federal jurisdiction are to be resolved against removal.” *In re Potash Antitrust Litig.*, 866 F. Supp. 406, 410 (D. Minn. 1994). “If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded.” 28 U.S.C. § 1447(c).

Alexander essentially argues that BCS and Guidant had no right to remove under 28 U.S.C. § 1441(a) because there is incomplete diversity of citizenship because St. Anthony’s is a Missouri resident. Alexander therefore argues that because there is no original jurisdiction, under 28 U.S.C. § 1447(c) the case must be remanded.

Here, because St. Anthony’s is a Missouri resident, the action on its face is not removable. Defendants assert, however, that removal was proper because Alexander fraudulently joined St. Anthony’s to defeat diversity jurisdiction. Under the doctrine of fraudulent joinder, joinder of a party that is designed solely to deprive federal courts of jurisdiction is deemed fraudulent and does not prevent removal. *Anderson v. Home Ins. Co.*, 724 F.2d 82, 84 (8th Cir. 1983). Fraudulent joinder does not require fraudulent intent; rather, fraudulent joinder exists if the plaintiff’s claim against an in-state defendant has no chance of success. *Schwenn v. Sears, Roebuck & Co.*, 822 F. Supp. 1453, 1455 (D. Minn. 1993); *see also Filla v. Norfolk S. Ry. Co.*, 336 F.3d 806, 809-10 (8th Cir. 2003) (stating that the Court must “determine whether there is a reasonable basis

for predicting that the state's law might impose liability against the defendant"); *Wiles v. Capitol Indem. Corp.*, 280 F.3d 868, 870 (8th Cir. 2002) ("Joinder is fraudulent and removal is proper when there exists no reasonable basis in fact and law supporting a claim against the resident defendant."); *Anderson*, 724 F.2d at 84 ("Fraudulent joinder exists if, on the face of plaintiff's state court pleadings, no cause of action lies against the resident defendant."). The burden is on the defendants to establish that a party has been fraudulently joined. *Schwenn*, 822 F. Supp. at 1455.

Guidant and BSC contend that the Court should find fraudulent joinder because Alexander failed to plead a cause of action against St. Anthony's. St. Anthony's similarly asserts that complete diversity exists because Alexander failed to state a claim against St. Anthony's. Specifically, Defendants assert that Alexander failed to plead any facts showing that St. Anthony's received the September 22, 2005 recall letter, and even if St. Anthony's did receive the letter, the letter did not instruct physicians to cease implantation of Model 1291 devices or ask for their return. In addition, Defendants assert that the December 12, 2005 Advisory Update states that the devices distributed after the recall letter were not subject to the recall, and therefore the device implanted in Alexander, which was manufactured in December 2005, was not subject to a recall on the date it was implanted.²

² The Court notes that the December 12, 2005 Advisory Update actually states that "Guidant *has recently discontinued* shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to 'Failure Mode 2,'" and that "INSIGNIA and NEXUS devices *currently being distributed by Guidant* are not subject to either failure mode and therefore are not included in either recall." (Williams Aff. at Ex. D (emphasis added).)

(Footnote Continued on Next Page)

St. Anthony also asserts that it does not owe a duty to patients to report that the manufacturer of certain devices used in its facilities is a party to litigation regarding products that are not being used with that particular patient. And, St. Anthony asserts that because Alexander has not plead any facts demonstrating that anyone at St. Anthony's assumed a duty to inform him of risks associated with his device, contending that Missouri law requires such assumption, Alexander has failed to state a claim against St. Anthony's.³

Alexander, on the other hand, asserts that he has a cause of action against St. Anthony's based on his allegations that St. Anthony's knew that model 1291 pacemakers were known to be dangerously defective by May 25, 2006, and knew that Guidant had recalled model 1291 pacemakers eleven months prior to his implantation yet continued to market the units. Alexander asserts that despite this knowledge, St. Anthony's—acting through its employees/agents—selected a model 1291 Guidant pacemaker to be implanted into Alexander. Alexander alleges that, prior to his implantation, St. Anthony's concealed all of this information from him.

(Footnote Continued From Previous Page)

This does not necessarily indicate that the devices distributed after the September 22, 2005 letter were not subject to the recall, as the Advisory Update does not give specific dates as to when those specific devices were discontinued and as to when distribution stopped.

³ BSC and Guidant also assert that to the extent Alexander's claim against St. Anthony's was a strict liability claim, the claim is foreclosed under Missouri law. Because Alexander concedes that his claim is not a strict liability claim, the Court does not address the issue here.

Alexander asserts that his allegations are supported by the fact that Guidant issued a recall regarding the model 1291 pacemakers on September 22, 2005, Guidant issued a separate recall regarding the model 1291 pacemakers within thirty days of his implantation, and as of the date of his implantation, hundreds of product liability lawsuits involving Guidant pacemakers were pending in state and federal courts. In addition, Alexander asserts that because “[St. Anthony’s] is in the business of implanting pacemakers and defibrillators and routinely does business with manufacturers and distributors of implantable cardiac devices,” St. Anthony’s “would certainly know the quality history and dependability rating of manufacturers selected by [St. Anthony’s] to supply pacemakers for implantation by [St. Anthony’s].” (Pl.’s Resp. in Opp’n to Def. St. Anthony’s Medical Center’s Mot. to Dismiss and to Def.’s Opp’n to Pl.’s Mot. to Remand to St. Louis County Circuit Court at 2.)

The Court acknowledges that Alexander is proceeding *pro se*. *Pro se* pleadings are liberally construed and are held to less stringent standards than formal pleadings drafted by lawyers. *See Martin v. Sargent*, 780 F.2d 1334, 1337 (8th Cir. 1985); *see also Estelle v. Gamble*, 429 U.S. 97, 106 (1976) (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972) (per curiam) (stating *pro se* complaints are held to less stringent standards than formal pleadings drafted by lawyers). Although BSC and Guidant contend that St. Anthony’s failure to warn claims are without factual basis because it was “factually impossible” for St. Anthony’s to have disclosed to Alexander that his device was potentially defective, the Court finds that, at this juncture, fact issues preclude the Court from finding that there is no basis for liability.

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"[C]ontested issues of fact should be resolved in favor of the plaintiff." *Schwenn*, 822 F. Supp. at 1455. Alexander alleges in his Complaint, among other things, that "the medical center does business with Guidant Corporation on a regular basis and routinely invites Guidant Corporation employees/agents into its operating rooms during the implanting of Guidant pacemakers for programming purposes." (Williams Aff., Ex. B at 4-5.) At a minimum, Alexander has raised an issue as to whether St. Anthony's knew or had reason to know that Alexander's device was recalled and/or potentially defective in light of the publicity Guidant had received prior to Alexander's implantation regarding potentially defective devices.

"Joinder is fraudulent only where there is no reasonable basis in fact or colorable ground supporting the claim against the resident defendant, or where the plaintiff has no real intention of prosecuting the action against the resident defendant." *Schwenn*, 822 F. Supp. at 1455. Here, Alexander's pleadings do allege facts, which if true, have a chance of success. At a minimum, in light of the liberal pleading requirements, the Court cannot conclude that no valid claims are brought against St. Anthony's as a matter of well-settled law. In addition, there is no evidence that St. Anthony's was singled out to avoid federal diversity jurisdiction rather than to obtain full relief. Accordingly, Alexander's joinder of St. Anthony's cannot be deemed fraudulent. Therefore, the Court concludes that because St. Anthony's was joined as a defendant, it lacks subject matter jurisdiction over this action as it currently stands.

Sever and Remand

To the extent the Court does find that St. Anthony's was not fraudulently joined, which the Court does find, BSC and Guidant alternatively request the Court to sever and remand Alexander's claims against St. Anthony's to state court and retain jurisdiction over Alexander's claims against BSC and Guidant. Specifically, BSC and Guidant assert that Alexander had fraudulently misjoined St. Anthony as a party, and therefore the claims against St. Anthony should be severed from the claims asserted against BSC and Guidant. BSC and Guidant contend that the claims arising out of St. Anthony's treatment do not arise out of the same transaction or occurrence as the claims against BSC and Guidant because the claims against St. Anthony's are based on medical negligence while the claims against BSC and Guidant are based on product liability. Alexander contends that his claims against St. Anthony's are not negated simply because his claims against BSC and Guidant are based on product liability. Alexander asserts that the Defendants' actions/inactions do arise out of the same transaction or occurrence.

The Federal Rules of Civil Procedure allow for permissive joinder of defendants as follows:

All persons . . . may be joined in one action as defendants if there is asserted against them jointly, severally, or in the alternative, any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action.

Fed. R. Civ. P. 20(b).⁴ If defendants have been misjoined for the failure to satisfy the conditions for permissive joinder under Rule 20(b), the Rules allow for severance of those defendants:

Misjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just. Any claim against a party may be severed and proceeded with separately.

Fed. R. Civ. P. 21.

Upon review of the applicable rules and the pleadings of the parties, the Court finds that St. Anthony's has been improperly joined in this case. The joinder of the malpractice claim against St. Anthony's with the other product liability claims was inappropriate because the claims do not both involve common questions of law or fact and assert joint, several, or alternative liability "arising out of the same transaction, occurrence, or series of transactions or occurrences." Fed. R. Civ. P. 20(b). Any liability that may be found against either BSC/Guidant or St. Anthony's would not be a basis for liability as to the other. However, separate liability as to each could be separately found.

This finding is consistent with how joinder has been interpreted in Missouri. The Missouri Supreme Court, for example, has rejected the propriety of joining defendants involved in successive accidents. *State ex rel. Jinkerson v. Koehr*, 826 S.W.2d 346, 348 (Mo. 1992) (en banc). There, the plaintiffs alleged they were seriously injured as a result of the successive negligent acts or omissions of the defendants "in combination" and that

⁴ The Missouri rule on permissive joinder is nearly identical to the federal rule and is identical in all relevant parts here. See Mo. R. Civ. P. 52.05.

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the two accidents “were not separate and distinct but inseparable and indistinguishable thereby creating common liability among all of the named defendants.” *Id.* at 346, 348. The supreme court held that joinder was not permitted under Mo. R. Civ. P. 52.05(a) because the cause of action arising out of the two accidents did not arise out the same transaction or occurrence. Instead, “[e]ach defendant [was] responsible for the injuries caused in the accident in which he or she was involved.” *Id.* at 348. In light of *Jinkerson*, the Court finds that it likely that the state court would find that Alexander did not have a reasonable basis for joining St. Anthony’s under state procedural law and that Alexander should sue St. Anthony’s under a separate state action.

Although some courts faced with fraudulent misjoinder claims have required both a finding of misjoinder and a finding of a bad faith attempt to defeat diversity, other courts have refused to apply the “egregious” standard when considering misjoinder in the context of remand petitions. *See In re: Baycol Products Litig.*, MDL No. 1431 (MJD), Case. No. 03-2931, 2003 WL 22341303, at *3 (D. Minn. 2003) (citing cases). The Eighth Circuit Court of Appeals has not addressed the issue.

Here, as the court in *Greene v. Wyeth* found, the Court “rejects the notion that Plaintiff[] ha[s] committed an egregious act or fraud upon the Court.” 344 F. Supp. 2d 674, 685 (D. Nev. 2004). “[U]nder our dual court system[, if] a potential plaintiff has a choice between a state forum and a federal forum, it is his privilege to exercise that choice subject to legal limitations, and if he can avoid the federal forum by the device of *properly* joining a non[-]diverse defendant or a non[-]diverse co-plaintiff, he is free to do so.” *Iowa Pub. Serv. Co. v. Med. Bow Coal Co.*, 556 F.2d 400, 406 (8th Cir. 1977)

(emphasis added). However, where a non-diverse party, such as St. Anthony's here, cannot be properly joined under the Federal Rules of Civil Procedure, other interests, such as the Defendants' statutory right of removal, prevail over that of permitting a plaintiff's choice of forum. *See Greene*, 344 F. Supp. 2d. at 685. Because the misjoinder of St. Anthony's would destroy complete diversity, and because the basis for the causes of action against St. Anthony's do not arise from the same transaction and occurrences as those in the causes of action against the other Defendants, the Court will sever the action against St. Anthony's so as to preserve BSC and Guidant's right to removal in the remaining action and to preserve the interests of judicial expediency and justice.

II. Motion to Dismiss

Because the Court concludes that the action against St. Anthony's shall be severed and remanded from the lawsuit, the Court denies St. Anthony's Motion to Dismiss as moot.

IT IS HEREBY ORDERED that:

1. Plaintiff Alexander's Motion for Remand to St. Louis County Circuit Court (MDL No. 05-1708 (DWF/AJB), Doc. No. 1258; Civil No. 07-1129 (DWF/AJB), Doc. No. 3) is **GRANTED** as to Defendant St. Anthony's Medical Center but **DENIED** as to all remaining Defendants. The Court Orders that all claims against Defendant St. Anthony's Medical Center are **SEVERED** and **REMANDED** to St. Louis County Circuit Court.

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2. Defendant St. Anthony's Motion to Dismiss (MDL No. 05-1708
(DWF/AJB), Doc. No. 1308; Civil No. 07-1129 (DWF/AJB), Doc. No. 9) is **DENIED**
AS MOOT WITHOUT PREJUDICE.

Dated: June 4, 2007

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court

EXHIBIT 7

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION**

LARRY AND CHARLOTTE HARDIN

Plaintiffs,

v.

GUIDANT CORPORATION, et al.,

Defendants.

§
§
§
§
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§
§
§

CIVIL ACTION NO. G-05-430

United States Court
Southern District of Texas
ENTERED

FEB 02 2006

Michael N. Milby, Clerk of Court

ORDER

This case came before the Court on February 1, 2006, for a routine scheduling conference. Pursuant to written briefing previously submitted to the Court and oral submissions by counsel at the scheduling conference, the Court **ORDERS** that all claims against Defendants Medical Center of Plano and J. Brian DeVille, M.D. are **SEVERED** and **REMANDED** to the District Court of Brazoria County, Texas, 239th Judicial District. All remaining proceedings are **STAYED PENDING TRANSFER** to the Hon. Donovan W. Frank of Minnesota for consolidation with other similar cases in MDL 1708.

IT IS SO ORDERED.

DONE this 1st day of February, 2006, at Galveston, Texas.



SAMUEL B. KENT
UNITED STATES DISTRICT JUDGE



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Clancy v. Zimmer, Inc.
W.D.N.Y., 2007.

Only the Westlaw citation is currently available.

United States District Court, W.D. New York.
Kathleen D. CLANCY and Richard M. Clancy,
Plaintiffs,
v.
ZIMMER, INC. and Cardinal Health 200, Inc.,
Defendants.
No. 04-CV-1018.

March 30, 2007.

[Brian G. Stamm](#), Stamm, Reynolds & Stamm,
Williamsville, NY, for Plaintiffs.
[Cheryl A. Heller](#), Ward, Norris, Heller & Reidy,
LLP, Rochester, NY, [Daniel Bartholomew Carroll](#),
[Timothy J. Fraser](#), Drinker Biddle & Reath LLP,
Florham Park, NJ, [Ethan Trull](#), Assistant General
Counsel, McGaw Park, IL, [Peter D. Braun](#), Phillips
Lytle LLP, Buffalo, NY, for Defendants.

ORDER

RICHARD J. [ARCARA](#), United States Chief District
Judge.

*1 This case was referred to Magistrate Judge H.
Kenneth Schroeder, Jr., pursuant to [28 U.S.C. §
636\(b\)\(1\)](#). Plaintiffs filed: (1) a motion to remand the
productsliability action against defendants Cardinal
Health 200, Inc. ("Cardinal") and Zimmer, Inc.
("Zimmer"), to New York State Supreme Court,
County of Erie ("State Court"); and (2) a motion to
join Dr. Wierzbieniec, Northtowns Orthopedics, P.C.
and Kaleida Health, d/b/a/ Millard Fillmore Suburban
Hospital as additional defendants and to remand this
matter to State Court. Defendant Cardinal moved for
summary judgment. Defendant Zimmer moved for
product identification discovery and extension of
time to respond to defendant Cardinal's motion for
summary judgment.

On February 8, 2007, Magistrate Judge Schroeder
filed a Report and Recommendation, recommending
that: (1) plaintiffs' motion to remand be denied; (2)
plaintiff's motion to join Dr. Wierzbieniec,
Northtowns Orthopedics, and Kaleida Health as

defendants be granted; (3) the case be remanded to
State Court pursuant to [28 U.S.C. § 1447\(e\)](#); and (4)
Cardinal's motion for summary judgment be denied,
without prejudice, to renewing it in State Court.

Defendants filed objections to the Report and
Recommendation on February 23, 2007. Oral
argument on the objections was held on March 29,
2007.

Pursuant to [28 U.S.C. § 636\(b\)\(1\)](#), this Court must
make a *de novo* determination of those portions of the
Report and Recommendation to which objections
have been made. Upon a *de novo* review of the
Report and Recommendation, and after reviewing the
submissions and hearing argument from the parties,
the Court adopts the proposed findings of the Report
and Recommendation.

Accordingly, for the reasons set forth in Magistrate
Judge Schroeder's Report and Recommendation, the
Court: (1) denies plaintiffs' motion to remand; (2)
grants plaintiff's motion to join Dr. Wierzbieniec,
Northtowns Orthopedics, and Kaleida Health as
defendants; (3) remands this case to State Court
pursuant to [28 U.S.C. § 1447\(e\)](#); and (4) denies,
without prejudice, Cardinal's motion for summary
judgment.

The Clerk of Court is directed to take all steps
necessary to close the case.

SO ORDERED.

REPORT, RECOMMENDATION AND ORDER^{[FN1](#)}

^{[FN1](#)} Since the Court of Appeals for the
Second Circuit has yet to determine whether
a motion to remand is a dispositive or
nondispositive motion, and the Hon. Richard
J. Arcara has previously declined to decide
the issue, the Court will avoid uncertainty
over the scope of its jurisdiction by
addressing the motion to remand by way of
Report, Recommendation and Order rather
than Decision and Order. Cf. [Vogel v. United
States Office Products Co.](#), 258 F.3d 509,

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514-517 (6th Cir.2001) (agreeing with Courts of Appeals in the Third and Tenth Circuits that motions to remand are dispositive motions), with In re Pfohl Bros. Landfill Litigation, 67 F. Supp. 2d 177, 179 (W.D.N.Y.1999) (declining to decide whether motion to remand is dispositive "because it would adopt the Magistrate Judge's decision to remand even under a *de novo* standard.") H. KENNETH SCHROEDER, JR., United States Magistrate Judge.

This matter was referred to the undersigned by the Hon. Richard J. Arcara, in accordance with 28 U.S.C. § 636(b), for all pretrial matters and to hear and report upon dispositive motions. Dkt. # 8. Currently before the Court is plaintiffs' motion to remand the **productsliability** action against defendants Cardinal Health 200, Inc. ("Cardinal"), and Zimmer, Inc. ("Zimmer"), to New York State Supreme Court, County of Erie (Dkt.# 5); plaintiffs' motion to join Dr. Wierzbieniec, Northtowns Orthopedics, P.C., and Kaleida Health, d/b/a Millard Fillmore Suburban Hospital ("Kaleida Health"), as additional defendants and, because **joinder** would destroy diversity, remand this matter to New York State Supreme Court, County of Erie (Dkt.# 22); Cardinal's motion for summary judgment (Dkt.# 33); and Zimmer's motion for product identification discovery and extension of time to respond to Cardinal's motion for summary judgment. Dkt. # 37.

*2 For the following reasons, it is recommended that plaintiffs' motion for **joinder** and remand be granted.

BACKGROUND

On February 5, 2004, plaintiffs filed a **medicalmalpractice** action (Index No.: I2004-1210), against Dr. Wierzbieniec, Northtowns Orthopedics, P.C., and Kaleida Health, d/b/a Millard Fillmore Suburban Hospital, in New York State Supreme Court, County of Erie. Dkt. # 5, p. 10. In their verified complaint, plaintiffs allege that Kathleen D. Clancy underwent a total right knee replacement performed by Dr. Wierzbieniec of Northtowns Orthopedics, P.C. at Millard Fillmore Suburban Hospital on November 15, 2001. Dkt. # 5, p. 15, ¶ 11. Approximately four days later, Dr. Wierzbieniec removed a drainage tube from the plaintiff's knee. Dkt. # 5, p. 15, ¶ 11. Plaintiff experienced pain at the surgical site and underwent an arthroscopic debridement and removal of two fragments of the

drainage tube by Dr. Wierzbieniec on July 16, 2002. Dkt. # 5, p. 16, ¶ 12. The pathology report from the arthroscopic debridement describes two tubular plastic fragments retained in plaintiff's leg. Dkt. # 5, p. 16, ¶ 12.

In their verified complaint, plaintiffs allege that Kathleen D. Clancy continued treatment with Dr. Wierzbieniec and Northtowns Orthopedics, P.C. until August of 2002. Dkt. # 5, p. 15, ¶ 9. In their verified bill of particulars, plaintiffs state that Kathleen D. Clancy continued to receive treatment from Northtowns Orthopedics, P.C. through December 16, 2002. Dkt. # 31, p. 8.

Plaintiffs' counsel affirms that during discovery with respect to the **medicalmalpractice** action, plaintiffs determined that a claim should be made against Zimmer and Cardinal. Dkt. # 5, p. 5, ¶ 9. "Due to the impending expiration of the Statute of Limitations," counsel affirms that "the Plaintiffs did not have time to request leave of Court to amend their original Summons and Complaint against the new Defendants." Dkt. # 5, p. 6, ¶ 9. Instead, plaintiffs commenced a separate **productsliability** action against Zimmer and Cardinal in State Supreme Court, County of Erie (Index No.: 2004-11761), on November 17, 2004, seeking \$1,000,000.00 on behalf of Kathleen D. Clancy and \$250,000.00 on behalf of Richard M. Clancy. Dkt. # 5, p. 22. Counsel affirms that plaintiffs intended to join the **productsliability** action against Zimmer and Cardinal with the pending **medicalmalpractice** action. Dkt. # 5, pp. 6-7, ¶ 11.

Zimmer, a Delaware corporation with its principal place of business in Indiana, removed the **productsliability** action to federal court on December 22, 2004. Dkt. # 1, p. 2, ¶ 4; Dkt. # 5, p. 24, ¶ 2. Cardinal, a Delaware corporation with its principal place of business in Illinois, consented to the removal. Dkt. # 1, p. 2, ¶ 3; Dkt. # 2 & Dkt. # 16, p. 1, ¶ 2.

DISCUSSION AND ANALYSIS

Motion to Remand ProductsLiability Complaint

Plaintiffs move to remand the **productsliability** complaint in the interest of justice and judicial economy so that it can be tried with the pending **medicalmalpractice** action. Dkt. # 5, ¶ 7. In support of their motion, plaintiffs' counsel avers that he chose

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to file a separate **productsliability** complaint against defendants Cardinal and Zimmer rather than move to amend the pending **medicalmalpractice** complaint because the statute of limitations was fast approaching when he first became aware of the potential liability of Cardinal and Zimmer. Dkt. # 5, ¶¶ 9-10, 12. Plaintiffs' counsel avers that he intended to move to consolidate the complaints, and notes that had there been sufficient time to move to amend the complaint, diversity jurisdiction would not have existed. Dkt. # 5, ¶ 12. Plaintiffs argue that they should not be forced to prosecute two actions arising from the same occurrence in separate forums. Dkt. # 5, ¶ 14.

*3 Defendants argue that the **productsliability** complaint was properly removed and that plaintiffs have offered no legal basis to warrant remand. Dkt. # 15.

[28 U.S.C. § 1332\(a\)\(1\)](#) provides:

The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between-
 (1) citizens of different States.

[28 U.S.C. § 1446](#), which sets forth the proper procedure for removal of an action to federal court provides that(a) A defendant or defendants desiring to remove any civil action or criminal prosecution from a State court shall file in the district court of the United States for the district and division within which such action is pending a notice of removal signed pursuant to [Rule 11 of the Federal Rules of Civil Procedure](#) and containing a short and plain statement of the grounds for removal, together with a copy of all process, pleadings, and orders served upon such defendant or defendants in such action.

(b) The notice of removal of a civil action or proceeding shall be filed within thirty days after the receipt by the defendant, through service or otherwise, of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based, or within thirty days after the service of summons upon the defendant if such initial pleading has then been filed in court and is not required to be served on the defendant, whichever period is shorter.

[28 U.S.C. § 1446\(a\) & \(b\)](#). Although there is no express statutory requirement that all defendants either join the petition for removal or consent to such

removal, there is widespread agreement among the district courts, including those in the Second Circuit, that all named defendants over whom the state court acquired jurisdiction must join in the removal petition for removal to be proper.” [Borden v. Blue Cross & Blue Shield of W.N.Y.](#), 418 F.Supp.2d 266, 269-70 (W.D.N.Y.2006). The party asserting diversity jurisdiction in federal court bears the burden of demonstrating that the action is properly before the federal court. *Id.*

In the instance case, plaintiffs are residents of New York seeking damages in excess of \$1,250,000.00 from Delaware corporations with principal places of business in Illinois and Indiana. Dkt. # 1, p. 2, ¶ 4; Dkt. # 16, p. 1, ¶ 2. Zimmer removed the **productsliability** complaint to this Court, with Cardinal's consent, within thirty days of being served with the Summons and Complaint. Dkt.1 & 2. As a result, the **productsliability** complaint is properly before this Court. Absent exceptional circumstances not presented here, federal courts may not abdicate their jurisdiction in favor of the concurrent jurisdiction of state courts. See [Colorado River Water Conservation Dist. v. United States](#), 424 U.S. 800, 817 (1976) (noting “the virtually unflagging obligation of the federal courts to exercise the jurisdiction given them.”); [Gregory v. Daly](#), 243 F.3d 687, 702 (2d Cir.2001) (maintenance of duplicate proceedings insufficient to warrant abstention); [American Disposal Servs., Inc. v. O'Brien](#), 839 F.2d 84, 87 (2d Cir.1988) (“existence of concurrent federal and state proceedings regarding the same subject matter is not by itself sufficient to justify dismissal”). Accordingly, plaintiffs' motion to remand the **productsliability** complaint (Dkt.# 5), should be denied.

Motion for Joinder and Remand

*4 Plaintiffs move to join Dr. Wierzbieniec, Northtowns Orthopedics, P.C., and Kaleida Health to the **productsliability** complaint and, because **joinder** will destroy diversity jurisdiction, remand the action to State Supreme Court. Dkt. # 22.

Defendants, Dr. Wierzbieniec and Northtowns Orthopedics, P.C., oppose the motion on the ground that the statute of limitations against these defendants expired no later than May 19, 2004 and the **medicalmalpractice** claims cannot relate back to the original state court proceeding. Dkt.25; 26 & 27. Defendant Kaleida Health takes no position on the

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motion. Dkt. # 30.

Plaintiffs reply that the allegations of **medicalmalpractice** against Dr. Wierzbieniec and Northtowns Orthopedics, P.C., are timely because plaintiff Kathleen Clancy received continuous treatment through December 16, 2002, thereby extending the statute of limitations. Dkt. # 31.

[28 U.S.C. § 1447\(e\)](#) provides:

If after removal the plaintiff seeks to join additional defendants whose **joinder** would destroy subject matter jurisdiction, the court may deny **joinder**, or permit **joinder** and remand the action to state court.

“The decision whether to admit the new parties is within the sound discretion of the trial court.” [Briarpatch Ltd., L.P. v. Pate](#), 81 F.Supp.2d 509, 515 (S.D.N.Y.2000).

In choosing the correct course, the court must first be satisfied that the additional defendants are permissive defendants under [Fed.R.Civ.P. 20](#). [Dieng v. Smith & Nephew Dyonics, Inc.](#), No. 02 CV 8201, 2003 WL 22240748, at *2 (S.D.N.Y. Sept. 29, 2003); see [Hunt v. Stryker Corp.](#), No. 03 Civ. 7385, 2004 WL 502186, at *2 (March 10, 2004); [Nazario v. Deere & Co.](#), 295 F.Supp.2d 360, 363 (S.D.N.Y.2003). [Fed.R.Civ.P. 20\(a\)](#) permits a **joinder** of multiple defendants in one action if there is asserted against the defendants “any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action.” [Fed.R.Civ.P. 20\(a\)](#). “Under this rule, ‘the impulse is toward the broadest possible scope of action consistent with fairness to the parties; **joinder** of claims, parties and remedies is strongly encouraged.” [Monicon v. Infra-Metals Corp.](#), No. 01 Civ. 11389, 2002 WL 31834442, at *2 (S.D.N.Y. Dec. 18, 2002), quoting [United Mine Workers of America v. Gibbs](#), 383 U.S. 715, 724 (1966). It is clear that these requirements are satisfied in the instant case, as **productsliability** and **medicalmalpractice** claims arising from the same medical procedure raise common questions of law and fact. See [Jedraszak v. Intromedix, Inc.](#), No. 00 CV 7566, 2004 WL 1497559, at *1 (S.D.N.Y. July 2, 2004); [Hunt](#), 2004 WL 502186, at *2; [Rodriguez v. Abbott Laboratories](#), 151 F.R.D. 529, 533 (S.D.N.Y.1993).

“In deciding whether to allow **joinder**, the Court is guided by the same standard of liberality afforded to motions to amend pleadings under Rule 15.” [Rush v. Artuz](#), No. 00 Civ. 3436, 2001 WL 1313465, at *5 (S.D.N.Y.2001) (internal quotation omitted); see [Clarke v. Fonix Corp.](#), No. 98 Civ. 6116, 1999 WL 105031, at *6 (S.D.N.Y. March 1, 1999), *aff’d* 199 F.3d 1321 (2d Cir.1999). [Fed.R.Civ.P. 15\(a\)](#) provides that a party may amend a pleading by leave of court or by written consent of the adverse party. Leave to amend is to be “freely granted” unless the party seeking leave has acted in bad faith, there has been an undue delay in seeking leave, there will be unfair prejudice to the opposing party if leave is granted, or the proposed amendment would be futile. [Foman v. Davis](#), 371 U.S. 178, 182 (1962); [State Teachers Retirement Bd. v. Fluor Corp.](#), 654 F.2d 843, 856 (2d Cir.1981); [Fed.R.Civ.P.15\(a\)](#).

*5 New York's Civil Practice Law and Rules provides that “[a]n action for medical, dental or podiatric malpractice must be commenced within two years and six months of the act, omission or failure complained of or last treatment where there is continuous treatment for the same illness, injury or condition which gave rise to the said act, omission or failure.” [N.Y. C.P.L.R. § 214-a](#). As a result, plaintiffs' August 30, 2005 motion to amend the **productsliability** action to incorporate allegations of **medicalmalpractice** arising from treatment rendered by Dr. Wierzbieniec no later than August of 2002 and by Northtowns Orthopedics, P.C. no later than December 16, 2002, is untimely unless it relates back to an original proceeding pursuant to [Fed.R.Civ.P. 15\(c\)](#). Dkt. # 5, p. 15, ¶ 9; Dkt. # 22; Dkt. # 31, p. 8.

[Fed.R.Civ.P. 15\(c\)](#) provides that
 An amendment of a pleading relates back to the date of the original pleading when

* * *

(2) the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth in the original pleading.

Pursuant to this provision, “the central inquiry is whether adequate notice of the matters raised in the amended pleading has been given to the opposing party within the statute of limitations by the general fact situation alleged in the original pleading. [Slayton v. American Express Co.](#), 460 F.3d 215, 228 (2d Cir.2006).

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In *Thompson v. Beth Israel Medical Center*, the district court determined that the definition of original pleading encompassed a separately filed state court pleading. No. 96 Civ. 0509, [1999 WL 228387, at *1 \(S.D.N.Y. April 19, 1999\)](#). The court explained that

Plaintiff's fourth cause of action, alleging false arrest and false imprisonment in violation of state law, is not dismissed as untimely. Plaintiff raised this claim in her *pro se* complaint filed in New York State Supreme Court on August 19, 1994 within the required statutory period of limitations. When a separately filed state court complaint against the Beth Israel Defendants was removed to federal court, plaintiff amended her federal complaint in March 1996 to include the claims against the City Defendants. These claims are not untimely merely because they were first made in federal court in March 1996 after the expiry of the statutory period of limitations. The City Defendants were clearly on notice of plaintiff's claims from the date the state court complaint was filed, and the allegations contained in the March 1996 amended complaint are deemed to relate back to the original state court complaint.

Id. In reaching this conclusion, the district court cited *Mueller v. Long Island R.R.*, in which the court rejected defendants' argument that amendment of a federal complaint to exercise supplemental jurisdiction over a **medicalmalpractice** claim would be futile, explaining that plaintiff filed a timely state claim for malpractice against the medical defendants. The allegations of the state complaint are identical to the allegations in the proposed amended complaint in this Court; as a result, the medical defendants were clearly on notice of the plaintiff's claim from the date the state court complaint was filed. Given that the "linchpin [of [Rule 15\(c\)](#)] is notice," *Schiavone v. Fortune*, 477 U.S. 21, 31 ... (1985), I conclude that plaintiff's proposed amendment relates back to the date of the original state court complaint against the medical defendants. Accordingly, plaintiff's proposed malpractice claim is not time-barred and the amendment is not futile.

*6 No. 89 Civ. 7384, [1997 WL 189123, at *5-6 \(S.D.N.Y. April 17, 1997\)](#). In *Hutchinson v. United States*, the district court relied upon *Mueller* to exercise supplemental jurisdiction over plaintiffs' **medicalmalpractice** claim and deny defendants' motion to dismiss the claim as barred by the statute

of limitations where a state court **medicalmalpractice** action, which was removed to federal court and dismissed without prejudice, placed defendants on notice of the **medicalmalpractice** claims. No. 01-CV-1198, [2004 WL 350576, at *6 \(E.D.N.Y. Feb. 20, 2004\)](#).

This court finds the analysis of these cases persuasive. As a result, the court determines that because the state court **medicalmalpractice** action was filed within the statute of limitations period and plaintiffs' proposed amendment to the **productsliability** complaint seeks to join the timely **medicalmalpractice** action, the allegations against the medical defendants relate back to the original state court complaint.

Having determined that **joinder** is not futile, the court must also consider whether **joinder** comports with principles of fundamental fairness by analyzing: (1) any delay, and the reasons for the delay, in seeking to amend; (2) any resulting prejudice to the defendants; (3) the likelihood of multiple litigation; and (4) the plaintiff's motivation in moving to amend. *Nazario*, 295 F.2d at 363; *Briarpatch*, 81 F.Supp.2d at 515. "Diversity-destroying **joinder** is permitted when the factors weigh in the moving party's favor." *Nazario*, 295 F.Supp.2d at 363.

Plaintiffs assert that they commenced a second suit rather than move to amend the original state court action so as to avoid concerns about the running of the statute of limitations, which was fast approaching upon discovery of the **productsliability** claim. Dkt. # 5, p. 6, ¶ 9. Plaintiffs aver that they intended to move to consolidate the complaints in state court, but were prevented from doing so by defendants' removal. Dkt. # 5, pp. 6-7, ¶ 11. This is an adequate explanation as to both the reason for the delay and plaintiffs' motivation in moving to amend. See *Dieng*, 2003 WL 22240748, at *1. With respect to prejudice, there is no indication that the defendants will not be afforded an adequate opportunity to prepare their defense to this action in the state courts. In any event, any prejudice which might arise from remand to state court "is outweighed by the danger of multiple litigation and the concomitant waste of judicial resources." *Id.* at *3. As plaintiffs aptly state, It is conceivable that the State Court Defendants will successfully place blame and liability on the Federal Court Defendants for the Plaintiff's [sic] serious injuries and damages while at the same time the Federal Court Defendants could successfully place

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the liability and blame on the State Court Defendants for the Plaintiffs [sic] injuries and damages which could severely effect the Plaintiffs [sic] ability to recover for her personal injuries and damages. Conversely, it is feasible that the Plaintiff [sic] could receive multiple verdicts and judgments from two different jury panels which could eventually lead to a double recovery for the Plaintiffs if they are successful in placing blame in Federal Court on the current Federal Court Defendants and in State Court on the current State Court Defendants.

*7 Dkt. # 22, p. 9. Accordingly, it is recommended that plaintiffs' motion to join Dr. Wierzbieniec, Northtowns Orthopedics, and Kaleida Health as additional parties be granted and, because joinder of these defendants destroys diversity, that this consolidated action be remanded to state court. Defendant Cardinal's motion for summary judgment and defendant Zimmer's motion for product identification discovery should be determined by the state court.

CONCLUSION

For the foregoing reasons, it is recommended that plaintiffs' motion (Dkt. # 5), to remand the **productsliability** complaint against Cardinal and Zimmer to New York State Supreme Court, County of Erie be **DENIED**; plaintiffs' motion (Dkt.# 22), to join Dr. Wierzbieniec, Northtowns Orthopedics, and Kaleida Health as defendants and remand the consolidated **productsliability** and **medicalmalpractice** action to New York State Supreme Court, County of Erie, pursuant to [28 U.S.C. § 1447\(e\)](#), be **GRANTED**; and Cardinal's motion (Dkt.# 33), for summary judgment and Zimmer's motion (Dkt.# 37), for product identification discovery and extension of time to respond to Cardinal's motion for summary judgment be **DENIED WITHOUT PREJUDICE** to renewing in New York State Supreme Court, County of Erie.

Accordingly, pursuant to [28 U.S.C. § 636\(b\)\(1\)](#), it is hereby

ORDERED, that this Report, Recommendation and Order be filed with the Clerk of the Court.

ANY OBJECTIONS to this Report, Recommendation and Order must be filed with the

Clerk of this Court within ten (10) days after receipt of a copy of this Report, Recommendation and Order in accordance with the above statute, [Fed.R.Civ.P. 72\(b\)](#) and Local Rule 72.3(a)(3).

The district judge will ordinarily refuse to consider *de novo* arguments, case law and/or evidentiary material which could have been, but was not presented to the magistrate judge in the first instance. See, e.g., [Patterson-Latch Co. v. Massachusetts Mun. Wholesale Electric Co.](#), 840 F.2d 985 (1st Cir.1988).

Failure to file objections within the specified time or to request an extension of such time waives the right to appeal the District Court's Order. [Thomas v. a/n.](#), 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985); [Wesolek v. Canadair Ltd.](#), 838 F.2d 55 (2d Cir.1988).

The parties are reminded that, pursuant to Rule 72.3(a)(3) of the Local Rules for the Western District of New York, "written objections shall specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for such objection and shall be supported by legal authority." *Failure to comply with the provisions of Rule 72.3(a)(3), or with the similar provisions of Rule 72.3(a)(2) (concerning objections to a Magistrate Judge's Report, Recommendation and Order), may result in the District Judge's refusal to consider the objection.*

The Clerk is hereby directed to send a copy of this Order and a copy of the Report and Recommendation to counsel for the parties.

***8SO ORDERED.**

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Not Reported in F.Supp.2d, 2004 WL 1497559 (S.D.N.Y.)

[Motions, Pleadings and Filings](#)

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United States District Court,
S.D. New York.
Marie JEDRASZAK and Edward Jedraszak, Plaintiffs,
v.
INTROMEDIX, INC., Semler Technologies, Inc., and Alaris Medical Systems, Inc., Defendants.
No. 00 CV 7566(GBD).
July 2, 2004.

Memorandum Decision and Order

[DANIELS](#), J.

***1** In a **product liability** action, plaintiffs are moving, pursuant to [28 U.S.C. § 1447](#), to join the defendants from an action presently pending in the Supreme Court of the State of New York, County of Westchester. Plaintiffs are requesting that if such joinder destroys federal diversity jurisdiction, the case be remanded to the New York State Supreme Court.

After undergoing a medical procedure at the Westchester County Medical Center, plaintiff Marie Jedraszak allegedly sustained post-operative injuries due to the application of a medical clamp. She and her husband, Edward Jedraszak, [FN1](#) commenced a medical **malpractice** action in the New York State Supreme Court in Westchester County. The defendants in that action are the physician who performed the procedure; the Westchester County Medical Center; and the County of Westchester, the municipality that owns and operates the hospital. Plaintiffs allege that, during discovery in the medical **malpractice** action, it was learned that those defendants may raise as a defense that the clamp was defective in its design, manufacture, and/or its training guidelines. As a result, plaintiffs commenced the instant action for **product liability** against the designers and manufacturers of the devices, *i.e.*, Intromedix, Inc., Semler Technologies, Inc., and Alaris Medical Systems, Inc. This separate case was filed in New York State Supreme Court, Orange County. Defendants removed the Orange County action to this federal court on the basis of diversity jurisdiction.

[FN1.](#) Mr. Jedraszak is asserting a derivative cause of action for loss of his wife's services.

None of the defendants in the Westchester County Supreme Court action are opposing the joinder motion. The defendant County of Westchester does object if the case is not remanded to the State Supreme Court in Westchester County. The Westchester defendant-physician seeks to have this case remanded to the Orange County Supreme Court. The only opposition to the motion seeking joinder is from defendant Alaris Medical Systems, Inc. also s/h/a Instromedix, Inc. ("Alaris").

Pursuant to [Fed.R.Civ.P. 20\(a\)](#), defendants may be joined in a single action if the asserted claims against them arise out of the same transaction or occurrence and the action will involve questions of law or facts common to all defendants. This rule seeks " 'to promote trial convenience and expedite the final determination of disputes, thereby preventing multiple lawsuits.' " See, [Corchado v. Product Design & Development, Inc., 2000 WL 134689, at *2 \(S.D.N.Y. Feb. 4, 2000\)](#) (quoting Charles Alan Wright et al., [7 Federal Practice and Procedure § 1652 at 372 \(2d ed.1986\)](#)). Merely because the legal theories

asserted in the cases are different does not prevent joinder. See, [Rodriguez v. Abbott Laboratories](#), 151 F.R.D. 529, 533 (S.D.N.Y.1993). "[M]edical **malpractice** and **product liability** claims arising out of the same medical procedure raise common questions of law and fact." See, [Hunt v. Stryker Corp.](#), 2004 WL 502186, at *2 (S.D.N.Y. Mar. 10, 2004). How the clamp was used, as well as questions regarding the proximate cause of plaintiff's alleged injuries, the extent of the injuries sustained, if any, and a determination of damages on both the primary causes of action and the derivative claim, are common issues of fact thereby satisfying the requirements of [Rule 20](#). See, [Dieng v. Smith & Nephew Dyonics, Inc.](#), 2003 WL 22240748, at *2 (S.D.N.Y. Sept. 29, 2003); [Rodriguez](#), 151 F.R.D. at 533; [Wilson v. Famatex GmbH Fabrik Fuer Textilausruestungsmaschinen](#), 726 F.Supp. 950, 951-52 (S.D.N.Y.1989).

***2** Joinder of the Westchester defendants to this action will destroy federal diversity jurisdiction. **Remand** of this action to New York State Court would therefore be required. Since joinder will destroy diversity jurisdiction, it must be still be determined whether permitting such joinder comports with the principles of fundamental fairness. See, [Rodriguez](#), 726 F.Supp. at 533; [Wilson](#), 726 F.Supp. at 952. Such a determination requires that the following factors be considered: the existence of a delay in seeking joinder, and the reason therefore; the resulting prejudice to defendant; the likelihood of multiple litigation; and the plaintiffs' motivation. See, [Hunt](#), 2004 WL 502186, at *2 (citations omitted).

Defendant Alaris claims that it will be prejudiced because substantial discovery has already been conducted in the Westchester County Supreme Court medical **malpractice** action. Such a claim is not a compelling reason to deny joinder in light of the fact that related issues will have to be litigated in two separate forums. See, [Rodriguez](#), 151 F.R.D. at 533. Defendant Alaris further claims it will not be afforded a sufficient opportunity to conduct its discovery. However, the Westchester County Supreme Court action was marked off calendar "in order to allow discovery to advance in the case subject to joinder." (Ryan Reply Aff. at 2). There is no good faith basis to believe that the state court will deny defendant Alaris appropriate discovery. See, [Dieng](#), 2003 WL 22240748, at * 3. Additionally, defendant Alaris argues that joinder will cause the other defendants in the Westchester County Supreme Court action to incur additional litigation costs.^{FN2} However, Alaris, as the sole defendant opposing joinder, proffers to specific facts to support its conclusory assertion that a joint action would be more costly for other defendants.

^{FN2}. Defendant Alaris contends that all the defendants will be prejudiced if plaintiffs' joinder motion is granted. As previously noted, none of the other defendants in either action have objected to joinder.

Finally, defendant Alaris argues that the primary purpose of plaintiffs' instant motion is to force a **remand** to their forum of choice. However, defendant Alaris fails to particularize any illegitimate motive on behalf of plaintiffs. "[W]here joinder would necessitate a **remand**, the court must determine whether the plaintiff seeking joinder is motivated primarily by a desire to force a **remand** to his [or her] forum of choice," See, [Wilson](#), 726 F.Supp. at 952. Here, there is no indication that plaintiffs are forum shopping. Defendant Alaris' conclusory assertions or implications of plaintiffs' improper motives is insufficient to defeat joinder. See, [Dieng](#), 2003 WL 22240748, at *3; [Soto v. Barnitt](#), 2000 WL 1206603, at *3 (S.D.N.Y. Aug. 23, 2000). It appears that plaintiffs' motivation is simply to recover from those parties that allegedly caused them to sustain damages. See, [Wyant v. Nat'l R.R. Passenger Corp.](#), 881 F.Supp. 919, 923 (S.D.N.Y.1995).

Simultaneous litigation of this matter in two different courts could cause unnecessary expense, conflicting results, a waste of judicial resources, and inconvenience to witnesses who must testify in both trials. See, [Rodriguez](#), 151 F.R.D. at 533. Accordingly, plaintiffs' motion to join the defendants who are in the Westchester County Supreme Court action is warranted.

***3** Since the joining of the parties destroys subject matter jurisdiction, the action cannot be litigated in

federal court. [28 U.S.C. § 1447\(e\)](#). Plaintiff seeks, in the alternative, to have the case remanded to the New York State Supreme Court in either Westchester County, the county where the medical **malpractice** action is presently pending, or Orange County, the county from where the case at bar was removed. Defendant County of Westchester opposes **remand** back to Orange County because New York law provides that the place of trial for all actions against it is in Westchester County. See, [N.Y. C.P.L.R. 504\(1\) \(McKinney 1976\)](#).

Remand by a federal court to a state county court from which the case was not originally removed is impermissible. A district court is to **remand** a case "to the State court from which it was removed." [28 U.S.C. § 1447\(d\)](#); [Petrofsky v. ARA Group, Inc., 878 F.Supp. 85 \(S.D.Tex.1995\)](#); see also, [Bloom v. Barry, 755 F.2d 356, 358 \(3d Cir.1985\)](#) (citation omitted) (" '**Remand**' means 'send back.' It does not mean 'send elsewhere.' The only **remand** contemplated by the removal statute is **remand** to the State court from which it was removed."). **Remand** of the instant case to the New York State Supreme Court, Orange County, from which it was removed, is required. Upon **remand**, defendant County of Westchester may then move that court to transfer the matter to Westchester County. See, [Roberti v. Longworth, 164 F.Supp.2d 395, 396 \(S.D.N.Y.2001\)](#); [Labrador v. Yamaha Motor Corp. U.S.A., 1992 WL 138400, at *1 \(E.D.N.Y. June 4, 1992\)](#).

Accordingly, plaintiffs' joinder motion is granted. Since joinder destroys federal diversity jurisdiction, the action is remanded back to the New York State Supreme Court, Orange County.

S.D.N.Y., 2004.

Jedraszak v. Intromedix, Inc.

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Motions, Pleadings and Filings [\(Back to top\)](#)

- [1:00cv07566](#) (Docket) (Oct. 05, 2000)

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Corchado v. Product Design & Development,
 Inc.
 S.D.N.Y., 2000.

Only the Westlaw citation is currently available.

United States District Court, S.D. New York.

Pablo CORCHADO, Plaintiff,

v.

PRODUCT DESIGN & DEVELOPMENT, INC.,
 Defendant.

No. 99 CIV. 9032(JSR).

Feb. 4, 2000.

MEMORANDUM ORDER

[RAKOFF](#), D.J.

*1 Plaintiff initially filed suit in New York State Supreme Court asserting against a company bearing a name similar to the name of the defendant here product liability claims for injuries allegedly caused by a defectively designed and manufactured hydraulic press. *See Pablo Corchado v. Product Design & Development Co. et al.*, Index No. 25351/98 (Nov. 23, 1998). In the same action, plaintiff also asserted medical malpractice claims against Mount Vernon Hospital and three of its doctors who treated his injuries. *Id.* Subsequently, plaintiff came to learn that the company that he had named in his initial action was not in fact the same company that had designed and manufactured the allegedly defective press. Rather than simply moving to amend his initial complaint to correct the error, plaintiff filed a separate complaint, also in state court, naming as the sole defendant the defendant here, which was the company that had actually designed and manufactured the hydraulic press in question. Plaintiff's plan was to move to consolidate the two state court actions, but before he could do so defendant timely removed the second action to federal court, pursuant to [28 U.S.C. § 1441](#), on grounds of diversity of citizenship. Plaintiff then moved to remand the action to state court pursuant to [28 U.S.C. § 1447\(c\)](#). Finding no legal basis to do so at that time, the Court denied plaintiff's motion to remand. *See* Order dated Nov. 15, 1999.

Meanwhile, however, plaintiff moved for compulsory

joinder of Mount Vernon Hospital under [Rule 19, Fed.R.Civ.P.](#), or, alternatively, for permissive joinder of Mount Vernon Hospital under [Rule 20, Fed.R.Civ.P.](#)^{FN1} Upon consideration of the parties' submissions, the Court, while denying plaintiff's motion for compulsory joinder under [Rule 19](#), grants plaintiff's motion for permissive joinder under [Rule 20](#). Since, moreover, both plaintiff and Mount Vernon Hospital are citizens of the State of New York, the effect of joining Mount Vernon Hospital to this action is to eliminate the Court's diversity jurisdiction over the subject matter of this action. *See* [28 U.S.C. § 1332](#). Accordingly, the Court remands the action to New York State Supreme Court pursuant to [28 U.S.C. § 1447\(e\)](#).

^{FN1} Plaintiff did not move to join any of three doctors named in the first state court action.

Compulsory joinder under [Rule 19, Fed.R.Civ.P.](#), is "designed to protect the interests of absent persons as well as those already before the court from multiple litigation or inconsistent judicial determinations," and therefore provides an exception to the general practice of allowing a plaintiff to choose who shall be parties to a lawsuit. *See* Charles Alan Wright et al., [7 Federal Practice and Procedure § 1602 at 18-21 \(2d ed.1986\)](#). To join an additional party under [Rule 19](#), the Court must first find that the additional party is a "necessary" party, for example, because in that party's absence complete relief cannot be accorded those persons already party to the action. *See* [Rule 19\(a\), Fed.R.Civ.P.](#) Assuming the additional party is "necessary," the Court must next find that joinder is "feasible." *See id.*; *see also Bank of America Nat'l Trust & Sav. Ass'n v. Hotel Rittenhouse Associates*, [844 F.2d 1050, 1053-54 \(3d Cir.1988\)](#). If the Court finds that joinder is not feasible—for example, because it would destroy the Court's diversity jurisdiction—the Court must then determine whether the additional party is "indispensable," in which case it must dismiss the entire action. *See* [Rule 19\(b\), Fed.R.Civ.P.](#); *see also Bank of America*, [844 F.2d at 1054](#).

*2 Here, plaintiff's basic theory is that defendant's machine caused his injuries and that the negligence

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of Mount Vernon Hospital and its doctors exacerbated those injuries. In such circumstances, Mount Vernon Hospital is not a “necessary” party under [Rule 19\(a\), Fed.R.Civ.P.](#) Even in the Hospital's absence, a jury can, if necessary, determine whether defendant's allegedly defective hydraulic press was a proximate cause of injury to plaintiff and what further injuries, if any, were the foreseeable result. See [Wilson v. Famatex GmbH Fabrik Fuer Textilausruestungsmaschinen](#), 726 F.Supp. 950, 952 n. 1 (S.D.N.Y.1989). Conversely, any such determination of liability would in no way prevent the absent Hospital and its doctors from separately defending the malpractice claims.

Moreover, even assuming *arguendo* that Mount Vernon Hospital were a “necessary” party under [Rule 19\(a\)](#), it would not in any case be an “indispensable” party under [Rule 19\(b\)](#) because, *inter alia*, a judgment rendered in the absence of Mount Vernon Hospital would not be sufficiently prejudicial to meet the requirements of [Rule 19\(b\)](#), either as to Mount Vernon Hospital, which could still defend itself against plaintiff's medical malpractice claims in the original state court action, or as to the initial defendant here, which could fully defend itself here against plaintiff's product liability claims even in the absence of Mount Vernon Hospital. Cf. [Rodriguez v. Abbott Laboratories](#), 151 F.R.D. 529, 532 n. 3 (S.D.N.Y.1993).

However, [Rule 20, Fed.R.Civ.P.](#), provides a more flexible test for joinder of additional parties. Specifically, [Rule 20](#) permits joinder of defendants in a single action if there is asserted against them any right to relief arising out of “the same transaction, occurrence, or series of transactions or occurrences” and involving “any question of law or fact common to all defendants.” [Rule 20\(a\), Fed.R.Civ.P.](#) Whereas [Rule 19](#) mainly seeks to protect the rights of absent parties, *see supra*, [Rule 20](#) attempts “to promote trial convenience and expedite the final determination of disputes, thereby preventing multiple lawsuits.” Charles Alan Wright et al., [7 Federal Practice and Procedure](#) § 1652 at 372 (2d ed.1986).

Here, it is evident that plaintiff's proposed joinder of Mount Vernon Hospital meets the formal requirements of [Rule 20](#) since his medical malpractice claims against the Hospital ultimately involve some of the same “series” of transactions or occurrences and some of the same “question[s] of fact” as his product liability claims against the instant

defendant. See [Rodriguez](#), 151 F.R.D. at 532-33 (permissive joinder of products liability and medical malpractice actions); [Wilson](#), 726 F.Supp. at 951 (same); cf. [Williams v. City of New York](#), 594 N.Y.S.2d 200 (App. Div. 1st Dep't 1993) (consolidation of negligence and medical malpractice actions). In practical terms, such joinder enables a single jury to determine in one action what portion, if any, of plaintiff's injuries is attributable to design defect and what portion to medical malpractice. Although in this case there would still be outstanding the original lawsuit against the three doctors, joinder of Mount Vernon Hospital, by bringing together the primary parties in one suit, would still substantially promote [Rule 20](#)'s goal of judicial economy and efficiency.

*3 Nonetheless, where, as here, permissive joinder would destroy the Court's subject matter jurisdiction, the Court must “carefully scrutinize the basis for joinder” to ensure that the proposed joinder of Mount Vernon Hospital “will comport with the principles of fundamental fairness,” [Rodriguez](#), 151 F.R.D. at 533, and that the party seeking joinder is not simply motivated by forum-shopping, *see id.* Here, however, upon review of the parties' submissions and representations at oral argument, *see transcript of Dec. 2, 1999*, the Court finds that it is obvious that plaintiff intended at all times to sue both the company and the hospital together, and that it was defendant who, taking advantage of plaintiff's clumsy manner of curing a technical error, engaged in forum-shopping. Cf. [Rodriguez](#), 151 F.R.D. at 533; [Wilson](#), 726 F.Supp. at 952.

Accordingly, while plaintiff's motion to join non-party Mount Vernon Hospital pursuant to [Rule 19](#) is denied, his motion to join to Mount Vernon Hospital pursuant to [Rule 20](#) is granted.^{FN2} Because, however, the joinder of the Hospital destroys the Court's subject matter jurisdiction, the Court hereby remands the action to state court. Clerk to enter judgment.

^{FN2}. In papers submitted at the invitation of the Court, non-party Mount Vernon Hospital argues that the Court should deny even permissive joinder because plaintiff's initial state court claims against the Hospital were dismissed by New York Supreme Court Judge Jerry L. Crispino for neglect to prosecute, *see Aff. in Opp.*, Ex. A, therefore barring a parallel action by plaintiff against Mount Vernon Hospital in this Court under

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the doctrine of *res judicata*, cf. [Rodriguez](#),
[151 F.R.D. at 532](#). However, on December
15, 1999, Judge Crispino granted plaintiff's
motion to vacate the dismissal against
defendant Mount Vernon Hospital (as well
as against the three doctors).*See* Letter of
Michael B. Doyle, dated Dec. 17, 1999. As a
result, the argument is moot, and the
doctrine of *res judicata* presents no bar to
joining Mount Vernon Hospital to the
instant action.

SO ORDERED.

S.D.N.Y.,2000.
Corchado v. Product Design & Development, Inc.
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(S.D.N.Y.)

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Dieng v. Smith & Nephew Dyonics, Inc.
 S.D.N.Y., 2003.

Only the Westlaw citation is currently available.

United States District Court, S.D. New York.

Abdou DIENG, Plaintiff,

v.

SMITH & NEPHEW DYONICS, INC., n/k/a Smith
 & Nephew Endoscopy, Inc. and Smith & Nephew,
 Inc. Defendant.

No. 02 CV 8201(RCC).

Sept. 29, 2003.

Patient brought **productsliability** action in state court against manufacturer of surgical device that broke off and became lodged in his knee during arthroscopic knee surgery. Following removal, plaintiff moved to amend complaint to add as defendants surgeon who performed operation and hospital in which surgery took place, and for remand on ground that such **joinder** destroyed diversity of citizenship. The District Court, Casey, J., held that: (1) surgeon and hospital were permissive defendants for purposes of **joinder**, and (2) **joinder** was fundamentally fair.

Motion granted.

West Headnotes

[11] Federal Civil Procedure 170A  266

[170A](#) Federal Civil Procedure

[170AII](#) Parties

[170AII\(F\)](#) Permissive **Joinder**

[170AII\(F\)2](#) Particular Parties Who May Be
 Joined

[170Ak266](#) k. Tort-Feasors in General.

[Most Cited Cases](#)

Surgeon who performed arthroscopic knee surgery during which surgical device broke off and became lodged in patient's knee, and hospital in which surgery took place, were permissive defendants for purposes of **joinder** in patient's **productsliability** action against manufacturer of surgical device, where patient's claims against defendants arose out of same surgical procedure, there were identical questions of

fact common to all defendants, and there were common questions of law with respect to causation and liability. [28 U.S.C.A. § 1447\(e\)](#); [Fed.Rules Civ.Proc.Rule 20\(a\)](#), [28 U.S.C.A.](#)

[21] Federal Civil Procedure 170A



266

[170A](#) Federal Civil Procedure

[170AII](#) Parties

[170AII\(F\)](#) Permissive **Joinder**

[170AII\(F\)2](#) Particular Parties Who May Be
 Joined

[170Ak266](#) k. Tort-Feasors in General.

[Most Cited Cases](#)

Federal Courts 170B



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[170B](#) Federal Courts

[170BIV](#) Citizenship, Residence or Character of
 Parties, Jurisdiction Dependent on

[170BIV\(B\)](#) Controversies Between Citizens
 of Different States

[170Bk303](#) k. Improper or Collusive
 Making or **Joinder** of Parties. [Most Cited Cases](#)

Joinder of surgeon who performed arthroscopic knee surgery during which surgical device broke off and became lodged in patient's knee, and hospital in which surgery took place, in patient's **productsliability** action against manufacturer of surgical device was fundamentally fair, since patient's delay in moving to join surgeon and hospital was not severe, permitting **joinder** would not prejudice defendants, and there was no evidence that patient sought **joinder** merely to destroy diversity of citizenship. [28 U.S.C.A. § 1447\(e\)](#).

MEMORANDUM & ORDER

CASEY, J.

*1 In this action, Plaintiff Abdou Dieng ("Plaintiff") brought suit in New York Supreme Court, Bronx County, against Defendant Smith & Nephew Dyonics, Inc. ("Defendant") for injuries Plaintiff sustained when a surgical device broke off and became lodged in his knee during [arthroscopic knee surgery](#). Defendant removed the case to this Court

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based on diversity of citizenship. Plaintiff now seeks leave to amend his complaint to include as defendants the surgeon who performed the operation and the hospital in which the surgery took place. Plaintiff further moves to remand this case to state court because such **joinder** would destroy diversity of citizenship and render this Court without subject matter jurisdiction. For the reasons stated below, the Court GRANTS Plaintiff's motion to join additional defendants and remand.

I. BACKGROUND

On July 31, 2001, Plaintiff, a citizen of New York, filed a **medicalmalpractice** suit in New York Supreme Court, Bronx County, against the physician who performed arthroscopic knee surgery on him, Dr. Zwi Weinberg ("Weinberg"), and against the hospital where the procedure occurred, Fifth Avenue Surgery Center ("Fifth Avenue"). (Affirmation in Support of Plaintiff's Motion to Join Additional Defendants and Remand ("Pl.'s Aff.") ¶ 3.) The complaint alleges that during the course of the operation, a piece of a surgical instrument known as a "grasper" broke off and became lodged in Plaintiff's knee. (*Id.* ¶ 2.) In August 2002, Plaintiff received information that the grasper was manufactured by Defendant, a corporation incorporated in Delaware and with its principal place of business in Tennessee. In October 2002, Plaintiff filed a separate suit against Defendant in New York Supreme Court with, according to Plaintiff's counsel, the intention of seeking to join the two state court actions. (*Id.* ¶ 4.) Before Plaintiff made such a motion, Defendant removed the case against it to this Court pursuant to [28 U.S.C. sections 1441\(a\)](#) and [1446\(a\)](#), based on diversity of citizenship between the parties. (*See* Defendant's Memorandum of Law in Opposition to Plaintiff's Motion ("Def.'s Mem.") at 3.)

On December 2, 2002, Plaintiff moved this Court to allow him to join Weinberg and Fifth Avenue as defendants in the instant action. Plaintiff further moves to remand the case to state court because Weinberg and Fifth Avenue are allegedly both citizens of New York, thus destroying diversity between the parties and rendering this Court without subject matter jurisdiction. (*See* Pl.'s Aff. ¶ 5.) Defendant opposes **joinder** and remand on the ground that granting Plaintiff's motion would result in consolidation of the two state court suits and prejudice Defendant because discovery in the state court proceedings against Weinberg and Fifth

Avenue was to be completed by November 6, 2002. (Def.'s Memo. at 5.) Thus, Defendant contends that it will have inadequate time to prepare a thorough defense in state court.

II. DISCUSSION

*2 When, as here, a plaintiff moves to join additional nondiverse defendants in a case removed from state court, a federal court may permit **joinder** and remand or deny **joinder**. [28 U.S.C. § 1447\(e\)](#). In choosing the correct course, the court must first be satisfied that the additional defendants are permissive defendants under [Federal Rule of Civil Procedure 20](#).^{FN1} Fulfilling [Rule 20](#)'s requirements, however, is not enough; the court must then ascertain whether **joinder** comports with principles of fundamental fairness. [Wilson v. Famatex GmbH Fabrik Fuer Textileausstattungsmaschinen](#), 726 F.Supp. 950, 952 (S.D.N.Y.1989). Examination of both these issues leads the Court to find that **joinder** and remand should be granted in this case.

^{FN1} Neither party contends that Weinberg and Fifth Avenue are necessary and indispensable parties, without whom the case against Defendant could not proceed. It is therefore sufficient to note that a plaintiff need not join all joint tortfeasors in the same suit. [Temple v. Synthes Corp.](#), 498 U.S. 5, 7, 111 S.Ct. 315, 112 L.Ed.2d 263 (1990) (per curiam). Thus, there is no issue of whether **joinder** would be mandatory in this case.

A. Permissive **Joinder** of Weinberg and Fifth Avenue as Defendants

[1][Federal Rule of Civil Procedure 20\(a\)](#) permits **joinder** of multiple defendants if there is asserted against them "any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action." [Fed.R.Civ.P. 20\(a\)](#). The actions against Defendant and Weinberg and Fifth Avenue arise out of the same surgical procedure performed on Plaintiff. In addition, identical questions of fact common to all defendants will inevitably arise in the action because resolution of Plaintiff's claims against each defendant will require, for example, determining whether the grasper actually broke during the operation as alleged, whether it remains lodged in

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Plaintiff's knee, and the injuries caused to Plaintiff by the operation. Finally, common questions of law abound because the causes of action alleged require resolution of identical legal issues such as causation and liability. *See Rodriguez v. Abbott Labs.*, 151 F.R.D. 529, 533 (S.D.N.Y.1993) (holding that **medical malpractice** and **products liability** claims arising out of same medical procedure raise common issues of law). Therefore, Weinberg and Fifth Avenue are permissible defendants in this suit.

B. Fundamental Fairness of Allowing Joinder of Weinberg and Fifth Avenue

[2] Courts in the Second Circuit use a four-part test in examining fundamental fairness in these circumstances. *See, e.g., Wyant v. Nat'l R.R. Passenger Corp.*, 881 F.Supp. 919, 923 (S.D.N.Y.1995); *Gursky v. Northwestern Mutual Life Ins. Co.*, 139 F.R.D. 279, 281 (E.D.N.Y.1991). First, courts consider any delay in moving to join additional defendants and the reasons for it; second, any resulting prejudice to the defendant; third, the threat of multiple litigation; and fourth, the plaintiff's motive for moving to amend. *Wyant*, 881 F.Supp. at 923; *Gursky*, 139 F.R.D. at 282. Applying this standard leads the Court to conclude that it is fundamentally fair to allow Plaintiff to join the additional defendants and have the cases remanded to state court.

Plaintiff filed his motion to join additional defendants on December 2, 2002; the case was removed from state court in October 2002. It appears that Plaintiff learned in August 2002 that Defendant manufactured the grasper used in his operation. (*See* Def.'s Memo. at 5.) Plaintiff states that he then commenced a second suit against Defendant because the statute of limitations did not leave him adequate time to move to amend the complaint against Weinberg and Fifth Avenue. (Pl.'s Aff. ¶ 4.) It appears that Plaintiff was concerned that the state court would not address a motion to amend before the statute of limitations on Plaintiff's claims against Defendant expired. Plaintiff additionally states that he intended to move to consolidate the suits in state court but that Defendant served notice of removal before he could do so. (*Id.*) The Court concludes that the delay in moving to join Defendant was not so severe as to weigh against granting Plaintiff's motion and that Plaintiff's explanation is adequate to explain why he did not seek to consolidate the related suits earlier.

*3 Defendant contends that permitting **joinder** and

remand now will greatly prejudice it because the proceedings in state court involving Weinberg and Fifth Avenue are too far along to allow Defendant adequate time to prepare a defense. However, Plaintiff submits that the only discovery that has occurred is a deposition of himself. Additionally, the state court proceedings appear to have been stayed pending resolution of Plaintiff's motion before this Court. (*See* Pl.'s Reply Affidavit ¶ 3, 4.) Given these facts, the Court finds no reason that Defendant will not have adequate time to prepare its defense. In addition, courts in this Circuit have expressly rejected the identical argument made by Defendant. *See Wyant*, 881 F.Supp. at 923; *Rodriguez*, 151 F.R.D. at 533. Any prejudice to Defendant that might remain is outweighed by the danger of multiple litigation and the concomitant waste of judicial resources. Denying **joinder** here would force Plaintiff to litigate the same issues simultaneously in federal and state courts. Such multiple litigation would serve neither the parties nor the courts.

Finally, there is no evidence that the Plaintiff seeks to join Defendant merely to destroy diversity. Instead, it is likely that Plaintiff wishes to join all defendants who may have contributed to the injuries he claims to have suffered in order to increase his chances of recovery and to expedite litigation. Bald assertions or implications that a plaintiff is motivated only to destroy diversity are insufficient proof of such motivation. *Soto v. Barnitt*, 2000 WL 1206603 at *3 (S.D.N.Y.2000) ("Where there is no evidence that **joinder** would be fraudulent or improper, this assertion, standing alone, is insufficient to defeat the **joinder**."); *accord Moncion v. Infra-Metals Corp.*, 2002 WL 31834442 at *3 (S.D.N.Y.2003). Therefore, Plaintiff's motivation for the motion does not weigh against granting **joinder** and remand.

Given the foregoing analysis, granting Plaintiff's motion comports with the precepts of fundamental fairness. Accordingly, Plaintiff's motion to join additional defendants and remand is hereby GRANTED. The clerk of the court is directed to close the case.

S.D.N.Y., 2003.

Dieng v. Smith & Nephew Dyonics, Inc.

Not Reported in F.Supp.2d, 2003 WL 22240748 (S.D.N.Y.)

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

*In re: Guidant Defibrillators
Products Liability Litigation*

Court File No. 05-md-1708

This pleading applies to:

ALL ACTIONS

**DEFENDANT GUIDANT CORPORATION'S ANSWER TO PLAINTIFFS' FIRST
AMENDED MASTER COMPLAINT FOR PERSONAL INJURY, ECONOMIC LOSS,
THIRD PARTY PAYOR AND MEDICARE SECONDARY PAYOR ACT CLAIMS,
INCLUDING CLASS ACTIONS**

Defendant Guidant Corporation ("Defendant") answers Plaintiffs' First Amended Master Complaint for Personal Injury, Economic Loss, Third Party Payor and Medicare Secondary Payor Act Claims, Including Class Actions ("Master Complaint") as follows:

Plaintiffs' Master Complaint improperly mixes factual averments with argumentative rhetoric so as to make admissions or denials of such averments difficult or impossible. Accordingly, by way of a general response, all allegations are denied unless specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, or speculations which are contained in the averment or in the Master Complaint as a whole.

Defendant further submits that the use of headings throughout the Master Complaint is improper and, therefore, no response to them is required. To the extent a response is required, and to the extent that such headings contain allegations directed toward Defendants, Defendant denies those allegations.

INTRODUCTION

1. Defendant admits that Plaintiffs bring this Master Complaint against Defendants for equitable, injunctive, and declaratory relief and monetary restitution and/or damages. Defendant denies that Plaintiffs' attempt to collectively refer to the separate entities named in Paragraph 1 as "Guidant" is correct, appropriate or has any legal significance whatsoever relative to Plaintiffs' claims and Plaintiffs' ability to seek relief or recover damages against the individual Defendants and denies that Plaintiffs are entitled to recover any relief whatsoever.

2. Defendant admits the allegations of Paragraph 2.

**SUMMARY OF GUIDANT MISCONDUCT
AND RESULTING DANGERS, DAMAGES, INJURIES, AND CLAIMS**

3. Defendant admits that this Master Complaint is filed on behalf of Plaintiffs presently in this MDL. Defendant denies the remaining allegations of Paragraph 3.

4. Defendant admits that in April 2006, its shareholders approved its acquisition by Boston Scientific Corporation ("Boston Scientific") and that on April 21, 2006, Boston Scientific's acquisition of Guidant Corporation was completed. Defendant denies the remaining allegations of Paragraph 4.

5. Defendant denies the allegations of Paragraph 5.

6. Defendant admits that the Master Complaint sets forth claims sounded in tort, contract, consumer and business protection statutes and equity but denies that Plaintiffs are entitled to any relief whatsoever. Defendant denies the remaining allegations of Paragraph 6.

7. Defendant admits that the Master Complaint sets forth the claims enumerated in Paragraph 7 but denies that Plaintiffs are entitled to any relief whatsoever.

8. Defendant denies the allegations of Paragraph 8.

9. Defendant admits that this Master Complaint includes claims of third-party persons such as health and welfare funds, self insured employers, and non-profit and for profit

health insurers, but states that these claims were dismissed by an Order of the Court dated April 16, 2007. Defendant denies the remaining allegations of Paragraph 9.

10. Defendant denies the allegations of Paragraph 10.

11. Defendant states that it has always treated patients and their medical professionals with forthrightness, respect, and candor. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11 and, therefore, denies the same.

12. Defendant admits that Paragraph 12 of the Master Complaint purports to set forth a table of contents for the Master Complaint.

PARTIES

Device Recipient Plaintiffs

13. Defendant admits upon information and belief that on or about April 10, 2003, Plaintiff John Boland was implanted with a CONTAK RENEWAL Model H135 cardiac resynchronization therapy defibrillator (“CRT-D”). Defendant further admits upon information and belief that on or about June 27, 2005, Plaintiff John Boland’s CONTAK RENEWAL Model H135 CRT-D was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 13. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 13 and, therefore, denies the same.

14. Defendant admits upon information and belief that on or about April 11, 2001, Decedent John Brennan was implanted with a VENTAK PRIZM 2 DR Model 1861 implantable cardioverter defibrillator (“ICD”). Defendant denies that it is liable for the injuries or damages

alleged in Paragraph 14. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 14 and, therefore, denies the same.

15. Defendant admits upon information and belief that on or about April 26, 2002, Plaintiff Christofer Brewster was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that on or about July 12, 2005, Plaintiff Christofer Brewster's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 15. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15 and, therefore, denies the same.

16. Defendant admits upon information and belief that in or around December 2002, Plaintiff Eugene Clasby was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant states upon information and belief that on or about May 4, 2006, Plaintiff Eugene Clasby's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 16. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 16 and, therefore, denies the same.

17. Defendant admits upon information and belief that on or about June 16, 1999, Plaintiff Paul Jones was implanted with a DISCOVERY DDDRO Model 1273 pacemaker. Defendant further admits upon information and belief that on or about August 8, 2005, Plaintiff Paul Jones' DISCOVERY DDDRO Model 1273 pacemaker was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 17. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 17 and, therefore, denies the same.

18. Defendant admits upon information and belief that on or about July 15, 2003, Plaintiff Zina Lewis was implanted with an INSIGNIA Plus DR Model 1297 pacemaker. Defendant further admits upon information and belief that on or about November 22, 2005, Plaintiff Zina Lewis' INSIGNIA Plus DR Model 1297 pacemaker was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 18. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 18 and, therefore, denies the same.

19. Defendant admits upon information and belief that on or about February 1, 2005, Plaintiff Judy Passante was implanted with a CONTAK RENEWAL 3 Model H170 CRT-D. Defendant further admits upon information and belief that on or about December 7, 2005, Plaintiff Judy Passante's CONTAK RENEWAL 3 Model H170 CRT-D was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 19. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 19 and, therefore, denies the same.

20. Defendant admits upon information and belief that on or about March 22, 2005, Plaintiff Mati Peleg was implanted with a VITALITY AVT Model A155 ICD. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 20. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 20 and, therefore, denies the same.

21. Defendant admits upon information and belief that on or about January 30, 2004, Decedent Marvin Schacher was implanted with a CONTAK RENEWAL Model H177 CRT-D. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 21. Defendant

is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 21 and, therefore, denies the same.

22. Defendant admits upon information and belief that on or about November 3, 2003, Plaintiff Thomas Shreiner was implanted with a VITALITY AVT Model A135 ICD. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 22. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 22 and, therefore, denies the same.

23. Defendant admits upon information and belief that on or about August 31, 2001, Plaintiff Heather Sorensen was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that on or about November 28, 2005, Plaintiff Heather Sorensen's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 23. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23 and, therefore, denies the same.

24. Defendant admits upon information and belief that on or about October 3, 2002, Plaintiff Oren Urich was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 24. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24 and, therefore, denies the same.

25. Defendant admits upon information and belief that in or around November 2002, Plaintiff Edith Walker was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that in or around September 2005, Plaintiff Edith Walker's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced.

Defendant denies that it is liable for the injuries or damages alleged in Paragraph 25. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 25 and, therefore, denies the same.

26. Defendant admits upon information and belief that on or about June 29, 2001, Plaintiff Larry Wenig was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that on or about August 3, 2005, Plaintiff Larry Wenig's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 26. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26 and, therefore, denies the same.

TPP Plaintiffs

27. Defendant states that the claims brought by Plaintiff UCFW Fund were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 27.

28. Defendant states that the claims brought by Plaintiff City of Bethlehem, Pennsylvania were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 28.

29. Defendant states that the claims brought by the self-styled "TPP Plaintiffs" were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 29.

MSP Plaintiff

30. Defendant states that the Medicare Secondary Payor Act (“MSP”) claims brought by Plaintiff Tamela Ivens were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 30.

Plaintiff Appearance In and Purpose Regarding the Master Complaint

31. Defendant generally admits that all the named Plaintiffs in the Master Complaint purport to bring this action in their individual and/or representative capacities on their own behalf or on behalf of all others similarly situated in order to obtain the relief sought herein, but denies that Plaintiffs are entitled to any such relief and denies that the named Plaintiffs have standing to assert claims on behalf of all others similarly situated. Defendant denies that class treatment is appropriate in this action and reserves the right to object to any individual who Plaintiffs may purport to offer as an appropriate class representative. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31 and, therefore, denies the same.

32. Defendant denies that Plaintiffs have standing to bring this lawsuit “as a public benefit action,” denies that this lawsuit will bring any “public benefit,” denies that Plaintiffs are entitled to any relief whatsoever, and denies the remaining allegations of Paragraph 32.

Defendants

33. Defendant admits that it is an Indiana corporation with its principal place of business at 111 Monument Circle, Indianapolis Indiana. Defendant further admits that the development, manufacture, and sale of ICDs, CRT-Ds, and pacemakers by its direct and indirect subsidiaries is collectively referred to as Cardiac Rhythm Management (“CRM”), and that CRM operations are principally conducted at 4100 Hamline Avenue North, St. Paul, Minnesota.

Defendant denies that it develops, researches, advertises, promotes, markets, or sells ICDs, or any devices, and denies the remaining allegations of Paragraph 33.

34. Defendant admits that Guidant Sales Corporation (“GSC”) is an Indiana Corporation with its principal place of business at 111 Monument Circle, Indianapolis, Indiana. Defendant further admits that GSC markets and sells ICDs and pacemakers manufactured by Cardiac Pacemakers, Inc. (“CPI”). Defendant states that GSC is a wholly-owned subsidiary of CPI. Defendant denies the remaining allegations of Paragraph 34.

35. Defendant admits that CPI is a Minnesota corporation with its principal place of business at 4100 Hamline Avenue North, St. Paul, Minnesota. Defendant further admits that CPI develops ICDs and pacemakers and that it is a wholly-owned subsidiary of Guidant Corporation. Defendant denies the remaining allegations of Paragraph 35.

36. Defendant admits that Boston Scientific is a Delaware corporation with its principal place of business in Natick, Massachusetts. Defendant further admits that in January 2006, Boston Scientific entered into an agreement to acquire Guidant Corporation and its subsidiaries for approximately \$27 billion. Defendant admits that the first sentence of Paragraph 36 purports to quote and/or characterize information found on Boston Scientific’s Internet website. Defendant states that the complete and precise content of that information can be ascertained from the website itself. Defendant denies the remaining allegations of Paragraph 36.

JURISDICTION AND VENUE

37. Defendant admits the allegations of Paragraph 37.

38. Defendant admits that venue is proper in this District. Defendant further admits that CPI has its principal place of business in this District. Defendant denies the remaining allegations of Paragraph 38.

FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

I. GUIDANT CORPORATE STRUCTURE

39. Defendant admits that CPI designs and manufacturers and that GSC markets and sells the cardiac medical devices at issue in this Master Complaint. Defendant denies the remaining allegations of Paragraph 39.

40. Defendant admits that GSC markets and sells the cardiac medical devices at issue in this Master Complaint. Defendant states that GSC is a wholly-owned subsidiary of CPI, which in turn is a wholly-owned subsidiary of Guidant Corporation. Defendant denies the remaining allegations of Paragraph 40.

41. Defendant admits that the allegations contained in the second sentence of Paragraph 41 purport to quote, characterize, and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant admits that GSC's marketing materials utilize the Guidant logo. Defendant denies the remaining allegations of Paragraph 41.

42. Defendant admits that Guidant Corporation's subsidiaries have their own officers. Defendant denies the remaining allegations of Paragraph 42.

43. Defendant admits that CPI's products include ICDs, pacemakers, and lead systems. Defendant generally admits the allegations in the second and third sentences of Paragraph 43. Defendant denies the remaining allegations of Paragraph 43.

44. Defendant admits that the allegations contained in the first sentence of Paragraph 44 purport to quote, characterize, and/or paraphrase the Corporate Overview Page at www.Guidant.com. Defendant states that the complete and precise content of that Internet web page can be ascertained from the website itself. Defendant generally admits the allegations in

the second and third sentences of Paragraph 44. Defendant states that the referenced financial information is publicly available and denies that the allegations of Paragraph 44 fairly or completely characterize that financial information.

II. OVERVIEW OF IMPLANTABLE DEVICES FOR CARDIAC RHYTHM MANAGEMENT

45. Defendant generally admits the allegations of Paragraph 45.

46. Defendant generally admits the allegations of Paragraph 46.

47. Defendant admits that the ICDs designed and manufactured by CPI and marketed and sold by GSC include the three components identified in Paragraph 47 of the Master Complaint. Defendant further states that ICDs are complex devices that contain many components and denies that the allegations of Paragraph 47 provide a complete or accurate representation of the components in an ICD.

48. Defendant generally admits the allegations of Paragraph 48.

49. Defendant generally admits the allegations of Paragraph 49.

50. Defendant states that, today, most defibrillators actually include both pacemaker and defibrillator functions. Defendant generally admits the remaining allegations of Paragraph 50.

51. Defendant generally admits the allegations of Paragraph 51 but states that a patient with an abnormal heart rate may be at risk of injury or death regardless of whether the patient's ICD or pacemaker delivers appropriate therapy.

52. Defendant admits that ICDs are intended to administer potentially life-saving therapy to patients with serious underlying heart conditions. Defendant further states that a patient's underlying heart condition can lead to death regardless of whether the patient's ICD delivers appropriate therapy.

53. Defendant generally admits the allegations of Paragraph 53.

54. Defendant generally admits the allegations of Paragraph 54.

55. Defendant generally admits the allegations of Paragraph 55. Defendant further states that a patient's underlying heart condition can lead to death regardless of whether the patient's pacemaker provides appropriate pacing.

56. Defendant denies the allegations of Paragraph 56.

III. DEVICES AT ISSUE

57. Defendant denies that Plaintiffs are entitled to any relief whatsoever.

58. Defendant denies that individuals who have been implanted with the ICDs and CRT-Ds described in Paragraph 58 are entitled to any relief whatsoever.

59. Defendant denies that individuals who have been implanted with the pacemakers described in Paragraph 59 are entitled to any relief whatsoever.

60. Paragraph 60 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that CPI has complied with all approval conditions pertaining to cardiac medical devices and denies the allegations of Paragraph 60.

61. Defendant denies that it has removed devices from the market. Defendant admits that certain communications to physicians involving the devices at issue have been classified as Class I or Class II recalls by the FDA.

62. Defendant admits that the allegations contained in paragraph 62 of Plaintiffs' Master Complaint purport to reference, interpret, and/or paraphrase a section of the Code of Federal Regulations ("C.F.R."). Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

63. Defendant admits that the allegations of Paragraph 63 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

64. Defendant admits that the allegations of Paragraph 64 purport to reference, interpret, and/or paraphrase a section of the United States Code (“U.S.C.”). Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

65. Defendant admits that the allegations of Paragraph 65 purport to reference, interpret, and/or paraphrase a section of the U.S.C. Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

66. Defendant admits that the allegations of Paragraph 66 purport to reference, interpret, and/or paraphrase a section of the U.S.C. Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

67. Defendant admits that the allegations of Paragraph 67 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

68. Defendant admits that the allegations of Paragraph 68 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

69. Defendant admits that the allegations of Paragraph 69 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

70. Defendant admits that the allegations of Paragraph 70 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

71. Defendant admits that the allegations of Paragraph 71 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

72. Paragraph 72 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that the allegations of Paragraph 72 purport to reference, interpret, and/or paraphrase certain FDA regulations. Defendant states that the complete and precise content of these regulations can be ascertained from the regulations themselves.

73. Defendant admits that the allegations of Paragraph 73 purport to reference, interpret, and/or paraphrase a July 18, 2002 approval letter and a section of the C.F.R. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves.

74. Defendant denies the allegations of Paragraph 74.

IV. HISTORY OF THE DEVICES

A. Summary

75. Defendant admits that CPI manufactured and that GSC promoted, sold, and distributed the devices at issue in this litigation. Defendant denies the remaining allegations of Paragraph 75.

76. Defendant denies the allegations of Paragraph 76.

77. Defendant denies the allegations of Paragraph 77.

78. Defendant admits that the allegations of Paragraph 78 purport to quote, characterize, and/or paraphrase a May 24, 2006 *New York Times* article. Defendant states that the complete and precise content of that article can be ascertained from the article itself. Defendant denies Plaintiffs' characterization of the article and denies the remaining allegations of Paragraph 78.

79. Defendant generally admits that the May 24, 2006 *New York Times* article referenced in Paragraph 79 attracted attention. Defendant denies the remaining allegations of Paragraph 79.

80. Defendant admits that CPI has issued several "Dear Doctor" and "Dear Patient" letters in order to provide current and accurate information to doctors and patients as this information is learned by CPI. Defendant denies that the information in these letters has been inconsistent, unclear, or incomplete. Defendant generally admits that some of CPI's recommendations have evolved over time as new information is learned. Defendant denies that device recipients and their medical advisors, as a group, remain confused and unclear as to the risks of the devices and the appropriate course of action to take. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 80 and, therefore, denies the same.

81. Defendant denies the allegations of Paragraph 81.

82. Defendant denies the allegations of Paragraph 82.

83. Defendant denies the allegations of Paragraph 83.

B. Ventak Prizm ICDs

84. Defendant denies the allegations of Paragraph 84.

85. Defendant denies the allegations of Paragraph 85..

86. Defendant admits that CPI first submitted the VENTAK PRIZM for approval in August 1996 pursuant to PMA P960040, and that Models 1810 and 1815 were originally approved for sale on July 18, 1997. Defendant further admits that the first implantation of the VENTAK PRIZM was announced on January 27, 1999. Defendant denies the remaining allegations of Paragraph 86.

87. Defendant admits that CPI sought approval of the VENTAK PRIZM 2 VR Model 1860 and VENTAK PRIZM 2 DR Model 1861 pursuant to PMA Supplement P960040 S015, and that CPI received notice of the approval of this PMA Supplement in August 2000. Defendant admits that GSC began selling the VENTAK PRIZM 2 DR Model 1861 in 2000. Defendant denies the remaining allegation of Paragraph 87.

88. Defendant admits the allegations of Paragraph 88.

89. Defendant admits that Paragraph 89 purports to quote, characterize, and/or paraphrase a May 25, 2005 press release and a June 14, 2005 *New York Times* article. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of these documents and denies the remaining allegations of Paragraph 89.

90. Defendant denies the allegations of Paragraph 90.

91. Defendant denies the allegations of Paragraph 91.

92. Defendant admits that explantation of an ICD involves a surgical procedure and that surgery involves certain risks including scarring. Defendant admits that ICDs are connected to the heart tissue with lead wires but denies that those lead wires need to be replaced in a typical explant surgery or that the presence of those lead wires appreciably increases the risks attendant to explant surgery.

93. Defendant denies the allegations of Paragraph 93.

94. Defendant admits that on May 20, 2002, following the third observed instance of arcing between the feedthrough wire and the backfill tube in a VENTAK PRIZM 2 DR Model 1861 ICD, CPI opened a “trend” to further investigate the instances of arcing. Defendant denies the remaining allegations of Paragraph 94.

95. Defendant admits that in April 2002, CPI made a manufacturing change to the VENTAK PRIZM 2 DR Model 1861. The change was intended to prevent the occurrence of arcing between the feedthrough wire and the backfill tube by ensuring appropriate spacing between the feedthrough wire and the backfill tube. The change involved placing medical adhesive between the feedthrough wire and backfill tube and allowing that medical adhesive to cure before proceeding with the remaining manufacturing steps. Defendant states that CPI complied with all FDA regulations pertaining to this manufacturing change. Defendant denies the remaining allegations of Paragraph 95.

96. Defendant admits that in November 2002, CPI made a manufacturing change to the VENTAK PRIZM 2 DR Model 1861. This change involved adding polyimide insulation to the backfill tube. Defendant states that CPI complied with all FDA regulations pertaining to this manufacturing change. Defendant denies the remaining allegations of Paragraph 96.

97. Defendant admits that the allegations of Paragraph 97 purport to quote, characterize, and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of this report can be ascertained from the report itself. Defendant denies Plaintiffs’ characterization of this report and denies the remaining allegations of Paragraph 97.

98. Defendant admits that the allegations of Paragraph 98 purport to quote, characterize, and/or paraphrase a June 2, 2005 *New York Times* article and a May 24, 2005 *New*

York Times article. Defendant states that the complete and precise content of these articles can be ascertained from the articles themselves. Defendant denies Plaintiffs' characterization of these articles and denies the remaining allegations of Paragraph 98.

99. Defendant admits that the trend report on the VENTAK PRIZM 2 DR Model 1861 was closed in April 2003. Defendant denies the remaining allegations of Paragraph 99.

100. Defendant admits that after April 2002, CPI continued to receive occasional reports of additional instances of arcing between the feedthrough wire and the backfill tube. Defendant admits that by February 2005 there had been 25 reported events of arcing between the feedthrough wire and the backfill tube. Defendant denies the remaining allegations of Paragraph 100.

101. Defendant admits that on March 14, 2005, a 21 year-old college student from Minnesota with hypertrophic cardiomyopathy, who had been implanted with a VENTAK PRIZM 2 DR 1861 ICD, collapsed and died. Defendant is without knowledge or information sufficient to admit or deny the allegations regarding the cause of death referred to in Paragraph 101 and, therefore, denies the same.

102. Defendant admits that physicians at the Minneapolis Heart Institute Foundation explanted the individual device referred to in Paragraph 102 and sent it to CPI for analysis. Defendant further admits that analysis confirmed that the device exhibited signs of arcing indicative of a short between the feedthrough wire and the backfill tube. Defendant further admits that the device had been disabled and that its memory was destroyed. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 102 and, therefore, denies the same.

103. Defendant is without knowledge of information sufficient to form a belief as to the truth of the allegations of the first sentence of Paragraph 103 and, therefore, denies the same. Defendant admits that representatives of CPI met with physicians from the Minneapolis Heart Institute Foundation on May 12, 2005. Defendant denies Plaintiffs' characterization of the meeting and denies the remaining allegations of Paragraph 103.

104. Defendant admits that Paragraph 104 refers to and purports to characterize and/or paraphrase a May 23, 2005 letter to physicians. Defendant denies Plaintiffs' characterization of this letter and denies the remaining allegations of Paragraph 104.

105. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 105 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 105. To the extent a response is required, Defendant admits that Guidant Corporation's Chief Medical and Technology Officer sold company stock but denies Plaintiffs' characterization of, and implication regarding the meaning of, such sales of stock. Defendant denies the remaining allegations of Paragraph 105.

106. Defendant admits that Paragraph 106 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 106.

107. Defendant admits that Paragraph 107 refers to and purports to selectively quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant

denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 107.

108. Defendant denies the allegations of Paragraph 108.

109. Defendant admits that CPI instituted a manufacturing change to replace polyimide insulation in the VENTAK PRIZM 2 DR Model 1861 with PEEK insulation because of rare instances of degrading of the polyimide insulation. Defendant denies the remaining allegations of Paragraph 109.

110. Defendant admits that CPI applied for and received FDA approval for the substitution of polyimide insulation with PEEK insulation. Defendant admits that the allegations of the second sentence of Paragraph 110 refer to and purport to quote, characterize, and/or paraphrase an October 13, 2005 FDA Notification. Defendant states that the complete and precise content of that notification can be ascertained from the notification itself. Defendant denies the remaining allegations of Paragraph 110.

111. Defendant admits that Paragraph 111 refers to and purports to quote, characterize, and/or paraphrase a May 25, 2005 press release. Defendant states that the complete and precise content of that press release can be ascertained from the press release itself. Defendant denies the remaining allegations of Paragraph 111.

112. Defendant admits that Paragraph 112 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 112.

113. Defendant admits that Paragraph 113 refers to and purports to quote, characterize, and/or paraphrase a July 1, 2005 FDA press release. Defendant states that the complete and precise content of that press release can be ascertained from the press release itself.

114. Defendant admits that Paragraph 114 refers to and purports to quote, characterize, and/or paraphrase an FDA report and a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of these documents and denies the remaining allegations of Paragraph 114.

115. Defendant denies the allegations of Paragraph 115.

C. Contak Renewal 1 and 2

116. Defendant admits that CPI manufactured the CONTAK RENEWAL Model H135 and the CONTAK RENEWAL 2 Model H155 CRT-Ds. Defendant denies the remaining allegations of Paragraph 116.

117. Defendant denies the allegations of Paragraph 117.

118. Defendant admits that Paragraph 118 purports to characterize and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 118.

119. Defendant denies the allegations of Paragraph 119.

120. Defendant denies the allegations of Paragraph 120.

121. Defendant admits that Paragraph 121 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and

precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 121.

122. Defendant admits that Paragraph 122 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 122.

123. Defendant admits that Paragraph 123 purports to characterize and/or paraphrase a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of that document can be ascertained from the document itself. Defendant denies Plaintiffs' characterization of the document and denies the remaining allegations of Paragraph 123.

124. Defendant admits that Paragraph 124 purports to characterize and/or paraphrase a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of that document can be ascertained from the document itself. Defendant denies Plaintiffs' characterization of the document and denies the remaining allegations of Paragraph 124.

125. Defendant admits that Paragraph 125 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

126. Defendant denies the allegations of Paragraph 126.

127. Defendant admits that Paragraph 127 refers to and purports to characterize and/or paraphrase a June 17, 2005 letter and a September 12, 2005 letter. Defendant states that the complete and precise content of these letters can be ascertained from the letters themselves.

128. Defendant admits that Paragraph 128 refers to and purports to characterize and/or paraphrase a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of that document can be ascertained from the document itself.

129. Defendant admits that Paragraph 129 purports to characterize and/or paraphrase an FDA recall notice. Defendant states that the complete and precise content of that notice can be ascertained from the notice itself.

130. Defendant admits that CPI learned of rare instances where the polyimide insulation in the CONTAK RENEWAL Model H135 and CONTAK RENEWAL 2 Model H155 degraded. Defendant denies that the rare instances of degrading observed in the polyimide insulation could, by themselves, result in short circuiting of the device. Defendant denies the remaining allegations of Paragraph 130.

131. Defendant denies the allegations of Paragraph 131.

132. Defendant admits that Paragraph 132 refers to and purports to quote, characterize, and/or paraphrase a December 2005 FDA report. Defendant states that the complete and precise content of that report can be ascertained from the report itself

133. Defendant denies the allegations of Paragraph 133.

D. Contak Renewal 3 and 4

134. Defendant admits that CPI manufactured the devices referenced in Paragraph 134.

135. Defendant denies the allegations of Paragraph 135.

136. Defendant admits that Paragraph 136 refers to and purports to quote, characterize, and/or paraphrase a June 23, 2005 letter to physicians and a June 30, 2005 FDA recall notice. Defendant states that the complete and precise content of these documents can be ascertained

from the documents themselves. Defendant denies Plaintiffs' characterization of these documents and denies the remaining allegations of Paragraph 136.

137. Defendant denies the allegations of Paragraph 137.

E. Ventak Prizm AVT, Vitality AVT, and Renewal AVT

138. Defendant admits that CPI manufactured the devices referenced in Paragraph 138. Defendant denies that the devices were "potentially defective" and denies the remaining allegations of Paragraph 138.

139. Defendant denies the allegations of Paragraph 139.

140. Defendant admits that Paragraph 140 refers to and purports to quote, characterize, and/or paraphrase June 17, 2005 and July 22, 2005 letters to physicians. Defendant states that the complete and precise content of these letters can be ascertained from the letters themselves. Defendant denies Plaintiffs' characterization of the letters and denies the remaining allegations of Paragraph 140.

141. Defendant admits that Paragraph 141 refers to and purports to quote, characterize, and/or paraphrase a July 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 141.

142. Defendant admits that Paragraph 142 refers to and purports to characterize and/or paraphrase a January 2006 statement from CPI. Defendant states that the complete and precise content of that statement can be ascertained from the statement itself. Defendant admits the allegations of the second sentence of Paragraph 142.

143. Defendant denies the allegations of Paragraph 143.

144. Defendant admits that Paragraph 144 refers to and purports to characterize and/or paraphrase an August 12, 2005 FDA recall notice. Defendant states that the complete and precise content of this notice can be ascertained from the notice itself.

145. Defendant denies the allegations of Paragraph 145.

F. Discovery, Pulsar, Meridian, Virtus, and Intelis Pacemakers

146. Defendant admits that CPI manufactures the pacemakers referenced in Paragraph 146.

147. Defendant denies the allegations of Paragraph 147.

148. Defendant admits that Paragraph 148 purport to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 148.

149. Defendant denies the allegations of Paragraph 149.

150. Defendant admits that Paragraph 150 refers to and purports to quote, characterize, and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 150.

151. Defendant admits that Paragraph 151 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 151.

152. Defendant admits that Paragraph 152 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise

content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 152.

153. Defendant admits that Paragraph 153 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians and a July 19, 1005 *New York Times* article. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of the documents and denies the remaining allegations of Paragraph 153.

154. Defendant admits that Paragraph 154 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

155. Defendant denies the allegations of Paragraph 155.

156. Defendant admits that Paragraph 156 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

157. Defendant admits that Paragraph 157 refers to and purports characterize and/or paraphrase an FDA recall notice. Defendant states that the complete and precise content of the notice can be ascertained from the notice itself.

158. Defendant admits that Paragraph 158 refers to and purports to characterize and/or paraphrase a January 23, 2006 letter to physicians. Defendant states that the complete and precise content of this letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 158.

159. Defendant denies the allegations of Paragraph 159.

G. Insignia and Nexus Pacemakers

160. Defendant denies the allegations of Paragraph 160.

161. Defendant denies the allegations of Paragraph 161.

162. Defendant denies the allegations of Paragraph 162.

163. Defendant admits that Paragraph 163 refers to and purports to quote, characterize, and/or paraphrase a September 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

164. Defendant admits that Paragraph 164 refers to and purports to characterize and/or paraphrase a September 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 164.

165. Defendant admits that Paragraph 165 refers to and purports to characterize and/or paraphrase a September 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 165.

166. Defendant admits that Paragraph 166 refers to and purports to characterize and/or paraphrase an FDA recall notice. Defendant states that the complete and precise content of that notice can be ascertained from the notice itself.

167. Defendant denies the allegations of Paragraph 167.

H. Pending Recalls

168. Defendant admits that CPI continues to follow FDA guidelines and communicate product information to doctors and patients as necessary. Defendant admits that the remaining allegations of Paragraph 168 refer to and purport to quote, characterize, and/or paraphrase a March 11, 2006 letter to physicians. Defendant states that the complete and precise content of

that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 168.

169. Defendant admits that Paragraph 169 refers to and purports to quote, characterize, and/or paraphrase a March 11, 2006 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

V. GUIDANT'S PAST AND PRESENT ILLEGAL AND REPREHENSIBLE CONDUCT

A. Guidant's Failure to Meet Basic Manufacturing & Regulatory Standards

170. Defendant admits that the FDA conducted an inspection of CPI's facilities during August 22, 2005 to September 1, 2005. Defendant further admits that at the conclusion of the inspection the FDA issued a 483 Inspection Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant denies the remaining allegations of Paragraph 170.

171. Defendant admits that Paragraph 171 refers to and purports to quote and/or characterize a February 8, 2006 FDA 483 Inspection Report. Defendant states that the complete and precise content of that report and be ascertained from the report itself.

172. Defendant admits that Paragraph 172 refers to and purports to quote, characterize, and/or paraphrase a February 8, 2006 FDA 483 Inspection Report. Defendant states that the complete and precise content of that report and be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 172.

173. Defendant denies the allegations of Paragraph 173.

174. Defendant admits that Paragraph 174 refers to and purports to quote, characterize, and/or paraphrase a February 8, 2006 FDA 483 Inspection Report. Defendant states that the

complete and precise content of that report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 174.

175. Defendant admits that Paragraph 175 purports to characterize and/or paraphrase February 8, 2006 and September 1, 2005 FDA 483 Inspection Reports. Defendant states that the complete and precise content of these reports can be ascertained from the reports themselves. Defendant denies the remaining allegations of Paragraph 175.

176. Defendant denies the allegations of Paragraph 176.

177. Defendant denies the allegations of Paragraph 177.

178. Paragraph 178 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 178

179. Defendant denies the allegations of Paragraph 179.

B. Guidant's Concealment of the Device Defects

180. Defendant denies the allegations of Paragraph 180.

181. Defendant denies the allegations of Paragraph 181.

182. Defendant denies the allegations of Paragraph 182.

183. Defendant denies the allegations of Paragraph 183.

184. Defendant denies the allegations of Paragraph 184.

185. Defendant admits that CPI regularly issues Product Performance Reports. Defendant denies the remaining allegations of Paragraph 185.

186. Defendant denies the allegations of Paragraph 186.

187. Defendant denies the allegations of Paragraph 187.

188. Defendant denies the allegations of Paragraph 188.

189. Defendant denies the allegations of Paragraph 189.

190. Defendant denies the allegations of Paragraph 190.

191. Defendant denies the allegations of Paragraph 191.

192. Defendant denies the allegations of Paragraph 192.

193. Defendant admits that Paragraph 193 refers to and purports to quote, characterize, and/or paraphrase a June 24, 2005 letter from Allan Gorsett. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 193.

194. Defendant admits that Paragraph 194 purports to characterize and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of the report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 194.

C. Guidant's Deceptive Promotional and Marketing Activities

195. Defendant denies the allegations of Paragraph 195.

196. Defendant admits that Paragraph 196 refers to and purports to depict an advertisement for an ICD. Defendant states that the complete and precise content of the advertisement can be ascertained from the advertisement itself. Defendant denies Plaintiffs' attempt to mischaracterize the advertisement or to take portions of it out of context.

197. Defendant admits that Paragraph 197 refers to and purports to depict and characterize an advertisement for an ICD. Defendant states that the complete and precise content of the advertisement can be ascertained from the advertisement itself. Defendant denies Plaintiffs' attempt to mischaracterize the advertisement or to take portions of it out of context. Defendant denies the remaining allegations of Paragraph 197.

D. Guidant's Continued Failure to Provide Adequate and Accurate Information

198. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 198 and, therefore, denies the same.

199. Defendant denies the allegations of Paragraph 199.

200. Defendant denies the allegations of Paragraph 200.

201. Defendant admits that some of the allegations of Paragraph 201 purport to characterize and/or paraphrase communications issued by CPI. Defendant states that the complete and precise content of these communications can be ascertained from the communications themselves. Defendant denies Plaintiffs' characterization of these communications and denies the remaining allegations of Paragraph 201.

202. Defendant admits that Paragraph 202 purports to characterize and/or paraphrase unidentified "FDA estimates." Defendant states that the complete and precise content of these "FDA estimates" can be ascertained from any such documents themselves. Defendant denies Plaintiffs' characterization of the documents and denies the remaining allegations of Paragraph 202.

203. Defendant admits that Paragraph 203 refers to and purports to quote, characterize and/or paraphrase June 17, 2005 and December 20, 2005 letters to physicians. Defendant states that the complete and precise content of these letters can be ascertained from the letters themselves. Defendant denies Plaintiffs' characterization of these letters and denies the remaining allegations of Paragraph 203.

E. Guidant's History of Criminal Misconduct

204. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 204 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which

is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 204. To the extent a response is required, Defendant admits that Paragraph 204 refers to and purports to quote, characterize, and/or paraphrase a plea agreement entered into by a separate and distinct corporate entity that is not a party to this lawsuit, Endovascular Technologies, Inc. Defendant states that the complete and precise content of the plea agreement can be ascertained from the agreement itself.

205. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 205 of the Master Complaint as “immaterial, impertinent, or scandalous matter” which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 205. To the extent a response is required, Defendant denies the allegations of Paragraph 205.

206. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 206 of the Master Complaint as “immaterial, impertinent, or scandalous matter” which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 206. To the extent a response is required, Defendant admits that Paragraph 206 refers to and purports to quote, characterize, and/or paraphrase a Corporate Integrity Agreement. Defendant states that the complete and precise content of this agreement can be ascertained from the agreement itself. Defendant denies Plaintiffs’ characterization of the agreement and denies the remaining allegations of Paragraph 206.

207. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 207 of the Master Complaint as “immaterial, impertinent, or scandalous matter” which is included solely for the purpose of harassment. Therefore, Defendant should not be required to

respond to Paragraph 207. To the extent a response is required, Defendant denies the allegations of Paragraph 207.

208. Defendant denies the allegations of Paragraph 208.

209. Defendant admits that Paragraph 209 purports to characterize and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 209.

210. Defendant admits that Paragraph 210 refers to and purports to characterize and/or paraphrase a June 16, 2005 *Minneapolis Star-Tribune* article. Defendant states that the complete and precise content of that article can be ascertained from the article itself. Defendant denies Plaintiffs' characterization of that article and denies the remaining allegations of Paragraph 210.

211. Defendant denies the allegations of Paragraph 211.

F. The Guidant Co-Defendants Are Agents and Alter Egos of One Another

212. Paragraph 212 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 212.

213. Paragraph 213 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 213.

214. Paragraph 214 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that CPI designed and manufactured and that GSC marketed and sold the cardiac medical devices at issue in this litigation. Defendant denies the remaining allegations of Paragraph 214.

215. Defendant denies the allegations of Paragraph 215.

216. Defendant denies the allegations of Paragraph 216.

217. Defendant admits that Boston Scientific has acquired Guidant Corporation. Defendant denies the remaining allegations of Paragraph 217.

VI. THE MEDICARE AS SECONDARY PAYER STATUTE

218. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 218.

219. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 219.

220. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 220.

221. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 221.

222. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 222.

223. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 223.

224. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 224.

225. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 225.

226. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 226.

227. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 227.

228. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 228.

229. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 229.

230. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 230.

231. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 231.

232. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 232.

233. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 233.

234. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 234.

235. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 235.

236. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 236.

237. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 237.

238. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 238.

239. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 239.

240. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 240.

241. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 241.

242. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 242.

243. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 243.

244. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 244.

245. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 245.

246. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 246.

247. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 247.

248. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 248.

249. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 249.

250. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 250.

251. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 251.

252. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 252.

253. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 253.

CLASS ACTION ALLEGATIONS

254. Defendant admits that Plaintiffs seek to bring this case on behalf of at least two proposed classes but denies that class treatment is appropriate in this case and denies that the proposed classes defined in Paragraph 254 of the Master Complaint are appropriate classes.

255. Defendant admits that Plaintiffs will seek class treatment for certain groups of Plaintiffs but denies that class treatment is appropriate in this case.

256. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 256 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

257. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 257 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

258. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 258 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

259. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 259 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

260. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 260 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

261. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 261 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

262. Paragraph 262 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 262.

263. Paragraph 263 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 263.

264. Paragraph 264 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 264.

265. Paragraph 265 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 265.

266. Paragraph 266 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 266.

267. Paragraph 267 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 267.

268. Paragraph 268 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 268.

269. Paragraph 269 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 269.

CLAIMS FOR RELIEF
DEVICE RECIPIENT PLAINTIFFS

270. Defendant denies that the Device Recipient Plaintiffs are entitled to any relief whatsoever.

COUNT I
STRICT LIABILITY – FAILURE TO WARN

271. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 270 as if fully set forth herein.

272. Defendant admits that CPI designed and manufactured and that GSC marketed and sold cardiac medical devices and that CPI and GSC were aware that the devices would be implanted in patients who suffered from the heart conditions for which the devices were indicated. Defendant denies the remaining allegations of Paragraph 272.

273. Defendant admits that the devices were expected to reach Plaintiffs' treating physicians without substantial change in their condition. Defendant is without knowledge or information sufficient to admit or deny that the devices reached Plaintiffs without substantial change in their condition as manufactured and sold. Defendant denies the remaining allegations of Paragraph 273.

274. Defendant denies the allegations of Paragraph 274.

275. Defendant is without knowledge or information sufficient to admit or deny that the devices were implanted and used in the manner for which they were intended and, therefore, denies the same. Defendant denies the remaining allegations of Paragraph 275.

276. Defendant denies the allegations of Paragraph 276.

277. Defendant denies the allegations of Paragraph 277.

COUNT II
STRICT LIABILITY – DESIGN AND/OR MANUFACTURING DEFECT

278. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 277 as if fully set forth herein.

279. Defendant denies the allegations of Paragraph 279.

280. Defendant denies the allegations of Paragraph 280.

281. Defendant admits that the devices were expected to reach Plaintiffs' treating physicians without substantial change in their condition. Defendant is without knowledge or information sufficient to admit or deny that the devices reached Plaintiffs without substantial change in their condition as manufactured and sold. Defendant denies the remaining allegations of Paragraph 281.

282. Defendant denies the allegations of Paragraph 282.

283. Defendant denies the allegations of Paragraph 283.

284. Defendant denies the allegations of Paragraph 284

285. Defendant denies the allegations of Paragraph 285.

286. Defendant denies the allegations of Paragraph 286.

COUNT III
NEGLIGENCE

287. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 286 as if fully set forth herein.

288. Defendant denies the allegations of Paragraph 288.

289. Defendant denies the allegations of Paragraph 289.

290. Defendant denies the allegations of Paragraph 290.

291. Defendant denies the allegations of Paragraph 291.

292. Defendant denies the allegations of Paragraph 292.

COUNT IV
NEGLIGENCE PER SE

293. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 292 as if fully set forth herein.

294. Paragraph 294 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal obligations and duties and denies the allegations of Paragraph 294.

295. Defendant denies the allegations of Paragraph 295.

296. Paragraph 296 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 296.

297. Defendant denies the allegations of Paragraph 297.

COUNT V
BREACH OF IMPLIED WARRANTY

298. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 297 as if fully set forth herein.

299. Defendant denies the allegations of Paragraph 299.

300. Defendant denies the allegations of Paragraph 300.

301. Defendant denies the allegations of Paragraph 301.

302. Defendant denies the allegations of Paragraph 302.

303. Defendant denies the allegations of Paragraph 303.

COUNT VI
FRAUD

304. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 303 as if fully set forth herein.

305. Defendant denies the allegations of Paragraph 305.

306. Defendant denies the allegations of Paragraph 306.

307. Paragraph 307 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal duties and denies the allegations of Paragraph 307.

308. Defendant denies the allegations of Paragraph 308.

309. Defendant denies the allegations of Paragraph 309.

COUNT VII
CONSTRUCTIVE FRAUD

310. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 309 as if fully set forth herein.

311. Defendant denies the allegations of Paragraph 311.

312. Defendant denies the conduct alleged and denies the remaining allegations of Paragraph 312.

313. Defendant denies the allegations of Paragraph 313.

314. Defendant denies the allegations of Paragraph 314.

315. Defendant denies the allegations of Paragraph 315.

COUNT VIII
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

316. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 315 as if fully set forth herein.

317. Paragraph 317 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal duties and denies the allegations of Paragraph 317.

318. Defendant denies the allegations of Paragraph 318.

319. Defendant denies the allegations of Paragraph 319.

320. Defendant denies the allegations of Paragraph 320.

321. Defendant denies the allegations of Paragraph 321.

322. Defendant denies the allegations of Paragraph 322.

323. Defendant denies the allegations of Paragraph 323.

324. Defendant denies the allegations of Paragraph 324.

325. Defendant denies the allegations of Paragraph 325.

326. Defendant denies the allegations of Paragraph 326.

COUNT IX
THE SENIOR CITIZEN AND HANDICAPPED PERSON CONSUMER FRAUD ACT
MINNESOTA STATUTE § 235F.71 AND/OR SIMILAR STATUTES IN EFFECT
IN OTHER JURISDICTIONS

327. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 326 as if fully set forth herein.

328. Paragraph 328 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that Paragraph 328 refers to and purports to characterize and/or paraphrase a section of the Minnesota statutes. Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

329. Paragraph 329 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that Paragraph 329 refers to and purports to characterize and/or paraphrase sections of the Minnesota statutes. Defendant states that the complete and precise content of the statutes can be ascertained from the statutes themselves.

330. Defendant denies the allegations of Paragraph 330.

331. Defendant denies the allegations of Paragraph 331.

332. Defendant denies the allegations of Paragraph 332.

333. Defendant denies the allegations of Paragraph 333.

334. Defendant denies the allegations of Paragraph 334.

335. Defendant denies the allegations of Paragraph 335.

336. Defendant denies the allegations of Paragraph 336.

337. Defendant denies the allegations of Paragraph 337.

338. Defendant denies the allegations of Paragraph 338.

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

339. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 338 as if fully set forth herein.

340. Defendant denies the allegations of Paragraph 340.

341. Paragraph 341 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal duties and denies the allegations of Paragraph 341.

342. Defendant denies the allegations of Paragraph 342.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

343. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 342 as if fully set forth herein.

344. Defendant denies the allegations of Paragraph 344.

345. Defendant denies the allegations of Paragraph 345.

346. Defendant denies the allegations of Paragraph 346.

347. Defendant denies the allegations of Paragraph 347.

COUNT XII
GROSS NEGLIGENCE/MALICE

348. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 347 as if fully set forth herein.

349. Defendant denies the conduct alleged, denies that Plaintiffs are entitled to exemplary damages or to any relief whatsoever, and denies the remaining allegations of Paragraph 349.

350. Defendant denies the conduct alleged, denies that Plaintiffs are entitled to exemplary damages or to any relief whatsoever, and denies the remaining allegations of Paragraph 350.

COUNT XIII
LOSS OF CONSORTIUM

351. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 350 as if fully set forth herein.

352. The allegations of Paragraph 352 are so nonsensical that Defendant is unable to provide a meaningful response. To the extent a response is required, Defendant denies the allegations of Paragraph 352.

353. Defendant denies the conduct alleged. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 353 and, therefore, denies the same.

354. Defendant denies that it is liable for the injuries alleged in Paragraph 354. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 354 and, therefore, denies the same.

355. Defendant denies that it is liable for the injuries alleged in Paragraph 355. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 355 and, therefore, denies the same.

356. Defendant denies that it is liable for the injuries alleged in Paragraph 356. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 356 and, therefore, denies the same.

357. Defendant denies the allegations of Paragraph 357.

COUNT XIV
WRONGFUL DEATH

358. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 357 as if fully set forth herein.

359. Defendant denies the allegations of Paragraph 359.

360. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 360 and, therefore, denies the same.

361. Defendant denies the allegations of Paragraph 361.

362. Defendant denies that Plaintiffs are entitled to any relief whatsoever. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 362 and, therefore, denies the same.

363. Defendant denies that Plaintiffs are entitled to the relief sought in Paragraph 363 or to any relief whatsoever.

COUNT XV
SURVIVAL ACTION

364. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 363 as if fully set forth herein.

365. Defendant denies the allegations of Paragraph 365.

366. Defendant denies that Plaintiffs are entitled to any relief whatsoever. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 366 and, therefore, denies the same.

367. Defendant denies that Plaintiffs are entitled to the relief sought in Paragraph 367 or to any relief whatsoever.

COUNT XVI
MEDICAL MONITORING

368. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 367 as if fully set forth herein.

369. Defendant denies the allegations of Paragraph 369.

370. Defendant denies the allegations of Paragraph 370.

COUNT XVII
UNJUST ENRICHMENT

371. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 370 as if fully set forth herein.

372. Defendant denies the allegations of Paragraph 372.

373. Defendant denies the allegations of Paragraph 373.

374. Defendant denies the allegations of Paragraph 374.

CLAIMS FOR RELIEF
THIRD PARTY PAYOR PLAINTIFFS

375. Defendant states that the claims brought by the Third Party Payor Plaintiffs were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 375. To the extent a response is required, Defendant denies that the Third Party Payor Plaintiffs are entitled to any relief whatsoever.

COUNT XVIII
VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICES ACT

By Order of this Court dated April 16, 2007, Count XVIII, the claim which is predicated upon Paragraph Nos. 376 through 386, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 376 through 386. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XIX
VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

By Order of this Court dated April 16, 2007, Count XIX, the claim which is predicated upon Paragraph Nos. 387 through 392, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 387 through 392. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XX
VIOLATION OF MINNESOTA FALSE STATEMENTS IN ADVERTISING STATUTE

By Order of this Court dated April 16, 2007, Count XX, the claim which is predicated upon Paragraph Nos. 393 through 398, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 393 through 398. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXI
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

By Order of this Court dated April 16, 2007, Count XXI, the claim which is predicated upon Paragraph Nos. 399 through 411, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 399 through 411. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXII
SUBROGATION LIABILITY DETERMINATION

By Order of this Court dated April 16, 2007, Count XXII, the claim which is predicated upon Paragraph Nos. 412 through 418, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 412 through 418. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXIII
UNJUST ENRICHMENT

By Order of this Court dated April 16, 2007, Count XXIII, the claim which is predicated upon Paragraph Nos. 419 through 427, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 419 through 427. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXIV
BREACH OF IMPLIED WARRANTY

By Order of this Court dated April 16, 2007, Count XXIV, the claim which is predicated upon Paragraph Nos. 428 through 432, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 428 through 432. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXV
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

By Order of this Court dated April 16, 2007, Count XXV, the claim which is predicated upon Paragraph Nos. 433 through 436, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 433 through 436. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXVI
MISREPRESENTATION BY OMISSION

By Order of this Court dated April 16, 2007, Count XXVI, the claim which is predicated upon Paragraph Nos. 437 through 443, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 437 through 443. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

CLAIMS FOR RELIEF
MEDICARE SECONDARY PAYOR PLAINTIFFS

444. Defendant states that the claims brought by the Medicare Secondary Payor Plaintiffs were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 444. To the extent a response is required, Defendant denies that the Medicare Secondary Payor Plaintiffs are entitled to any relief whatsoever.

COUNT XXVII
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

By Order of this Court dated April 16, 2007, Count XXVII, the claim which is predicated upon Paragraph Nos. 445 through 448, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 445 through 448. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXVIII
LIABILITY AS FIRST-PARTY INSURER UNDER MSP: AGREEMENT TO PAY MEDICAL COSTS

By Order of this Court dated April 16, 2007, Count XXVIII, the claim which is predicated upon Paragraph Nos. 449 through 455, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 449 through 455. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXIX
LIABILITY AS FIRST PARTY INSURER UNDER MSP: PROVISIONS OF EXPRESS AND IMPLIED WARRANTIES

By Order of this Court dated April 16, 2007, Count XXIX, the claim which is predicated upon Paragraph Nos. 456 through 462, was dismissed by the Court and, therefore, no response is

required to the allegations of Paragraph Nos. 456 through 462. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXX
LIABILITY AS THIRD PARTY INSURER UNDER MSP: LIABILITY AS HOLDER OF
A LIABILITY INSURANCE POLICY OR PLAN

By Order of this Court dated April 16, 2007, Count XXX, the claim which is predicated upon Paragraph Nos. 463 through 470, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 463 through 470. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXXI
PUNITIVE DAMAGES

471. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 470 as if fully set forth herein.

472. Defendant denies that Plaintiffs are entitled to punitive and/or exemplary damages or to any relief whatsoever and denies the remaining allegations of Paragraph 472.

Defendant denies that Plaintiffs are entitled to the relief requested in the Prayer for Relief or to any relief whatsoever.

AFFIRMATIVE AND OTHER DEFENSES

Having answered the allegations of the Plaintiffs' First Amended Master Complaint and having denied any liability whatsoever, Defendant further denies any allegations that have not been expressly admitted and asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

At no time has Defendant Guidant Corporation participated in any way in the design, manufacture, assembly, marketing, or sale of the products described in Plaintiffs' Complaint. Guidant Corporation is an improper party to this action and should be dismissed.

SECOND AFFIRMATIVE DEFENSE

Defendant Guidant Corporation states that it never designed, manufactured, advertised or sold the medical devices at issue in this litigation in the State of Minnesota, or anywhere else. This Court lacks personal jurisdiction over Guidant Corporation and any assertion of personal jurisdiction over Guidant Corporation violates its rights under the Due Process Clause of the Fourteenth Amendment of the United States Constitution.

THIRD AFFIRMATIVE DEFENSE

The devices to which Plaintiffs refer in the Master Complaint are Class 3 prescription medical products. The federal government has preempted the field of law applicable to the design, testing, and labeling of prescription medical products. Plaintiffs' cause of action, therefore, fails to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

FOURTH AFFIRMATIVE DEFENSE

At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and the state-of-the-art in existence at the time.

FIFTH AFFIRMATIVE DEFENSE

The devices at issue in this case are prescription medical products that fall within the “comment k” and “comment j” exceptions to strict liability, as defined in Restatement (Second) of Torts §402A. The benefits of the devices outweigh the risks, if any, which may be attendant to their use. The devices are therefore neither defective nor unreasonably dangerous.

SIXTH AFFIRMATIVE DEFENSE

The devices at issue in this case are prescription medical products that fall within Restatement Third, Torts: Products Liability § 6. Therefore, the devices are reasonably safe in design if a reasonable healthcare provider would prescribe the devices for any class of patients knowing the foreseeable risks and therapeutic benefits.

SEVENTH AFFIRMATIVE DEFENSE

Under the learned intermediary defense, the manufacturer of a prescription medical device is to provide warnings and appropriate information only to the prescribing physician and the medical profession, which act as “learned intermediaries” in determining the use of the product for a particular patient. To the extent Plaintiffs assert that Defendant failed to provide Plaintiffs with adequate warnings regarding the use of the device, any obligation to warn was discharged when adequate warnings were provided to Plaintiffs’ or Plaintiffs’ Decedents’ treating and prescribing physicians. Plaintiffs’ claims are also barred by the Sophisticated User Doctrine, or similar applicable laws.

EIGHTH AFFIRMATIVE DEFENSE

Defendant believes, and upon that ground alleges, that Plaintiffs or Plaintiffs’ Decedents were advised of the risks associated with the matters alleged in Plaintiffs’ Master Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk,

informed consent, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

NINTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, may have resulted from an intervening cause or causes, and any action on the part of Defendant was not the proximate or competent producing cause of Plaintiffs' alleged injuries.

TENTH AFFIRMATIVE DEFENSE

The conduct of Defendant and the subject products conformed with the Federal Food, Drug, and Cosmetic Act and the requirements of the Food and Drug Administration. Moreover, Defendant's activities conformed with state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by the applicable statutes of limitations and statutes of repose.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by the doctrines of waiver, estoppel, and laches.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' breach of warranty claims are barred because there is no privity of contract between Plaintiffs and Defendant; Plaintiffs failed to give timely notice of any alleged breach of warranty to Defendant; Plaintiffs did not reasonably rely upon any alleged warranty; Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries occurred, if at all, because of circumstances and conditions beyond the control of Defendant.

SIXTEENTH AFFIRMATIVE DEFENSE

This action cannot be maintained as a class action because it does not meet the requirements to be certified as a valid class action set forth in Rule 23 of the Federal Rules of Civil Procedure and as further explained in the case law.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because any labeling with respect to the subject product was not false or misleading and, therefore, constitutes protected commercial speech under the applicable provisions of the United States Constitution and the Constitutions of the 50 states.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution because they purport to regulate interstate commerce and impermissibly place an undue burden on interstate commerce.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to satisfaction under the consumer protection laws of Minnesota or any other state because Plaintiffs cannot satisfy the elements of these statutes and because Plaintiffs lack standing to assert claims under these statutes.

TWENTY-FIRST AFFIRMATIVE DEFENSE

While denying at all times that Plaintiffs have stated a valid claim under Minnesota consumer protection statutes or the consumer protection statutes of any other state, to the extent such claims are found to exist, Defendant pleads all defenses available under those statutes and states that any such claims are limited by the provisions of the statutes.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims fail to state a cause of action and fail to state claims for which relief may be granted.

TWENTY-THIRD AFFIRMATIVE DEFENSE

The claims asserted in the Complaint are barred, in whole or in part, because the utility of the device at issue outweighs the alleged risk.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Defendant is entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other person or entity.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendant's rights under the United States Constitution and analogous provisions of Constitutions of the 50 states.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

At all relevant times, herein, Plaintiffs' or Plaintiffs' Decedents' prescribing physicians were in the position of a sophisticated purchaser, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for fraud are barred because Plaintiffs have failed to specifically aver such claims as required by Federal Rule of Civil Procedure 9(b).

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

No act or omission of Defendant was malicious, willful, wanton, reckless, grossly negligent, or intentional and, therefore, any award of punitive damages is barred.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Punitive damages are not appropriate in this case and any claim for punitive damages contravenes the rights of Defendant under each of the following constitutional provisions: the Due Process Clause and the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Equal Protection Clause and Due Process Clause of the Fourteenth Amendment of the United States Constitution; the Constitutions of the 50 states; and the law, statutes, rules and policies of the 50 states given the circumstances of this litigation, including but not limited to:

- (a) imposition of punitive damages by a jury which

- (1) is not provided with standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award;
- (2) is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment;
- (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, or state of residence of Defendant;
- (4) is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; and
- (5) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards;

(b) imposition of such punitive damages, and determination of the amount of an award thereof, where applicable state law is impermissibly vague, imprecise, or inconsistent;

(c) imposition of such punitive damages, and determination of the amount of an award thereof, without bifurcating the trial and trying all punitive damages issues only if and after the liability of Defendant has been found on the merits;

(d) imposition of such punitive damages, and determination of the amount of an award thereof, based on anything other than Defendant's conduct in connection with the sale of

the products alleged in this litigation, or in any other way subjecting Defendant to impermissible multiple punishment for the same alleged wrong.

THIRTIETH AFFIRMATIVE DEFENSE

Any claim for punitive damages in this case cannot be sustained to the extent it seeks to punish Defendant for alleged harm to non-parties and/or persons who are not before the Court. Imposition of punitive damages under such circumstances would violate Defendant's procedural and substantive due process rights and equal protection rights under the Fifth and Fourteenth Amendments to the United States Constitution and Defendant's due process and equal protection rights under cognate provisions of the Constitutions of the 50 states, and would be improper under the common law and public policies of the United States and the 50 states.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because equitable relief is not available under any of the alleged causes of action.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because Plaintiffs have an adequate remedy at law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Complaint because the hardship that would be imposed on Defendant by the relief is greatly disproportionate to any hardship that Plaintiffs might suffer in its absence.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Complaint because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Defendant expressly reserves the right to amend this Answer to assert additional defenses or to make additional claims for relief as discovery in this action should warrant.

JURY DEMAND

Defendant hereby requests a jury trial as to all claims triable in this action.

PRAYER FOR RELIEF

WHEREFORE, Defendant prays for relief from judgment from Plaintiffs as follows:

1. Plaintiffs take nothing by reason of this Master Complaint;
2. Defendant recovers its costs, and attorneys' fees incurred herein;
3. For a trial by jury on all issues so triable; and
4. For such further and other relief as the Court deems proper.

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

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ATTORNEYS FOR DEFENDANT
GUIDANT CORPORATION

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

*In re: Guidant Defibrillators
Products Liability Litigation*

Court File No. 05-md-1708

This pleading applies to:

ALL ACTIONS

**DEFENDANT GUIDANT SALES CORPORATION'S ANSWER TO PLAINTIFFS'
FIRST AMENDED MASTER COMPLAINT FOR PERSONAL INJURY, ECONOMIC
LOSS, THIRD PARTY PAYOR AND MEDICARE SECONDARY PAYOR ACT
CLAIMS,
INCLUDING CLASS ACTIONS**

Defendant Guidant Sales Corporation ("GSC" or "Defendant") answers Plaintiffs' First Amended Master Complaint for Personal Injury, Economic Loss, Third Party Payor and Medicare Secondary Payor Act Claims, Including Class Actions ("Master Complaint") as follows:

Plaintiffs' Master Complaint improperly mixes factual averments with argumentative rhetoric so as to make admissions or denials of such averments difficult or impossible. Accordingly, by way of a general response, all allegations are denied unless specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, or speculations which are contained in the averment or in the Master Complaint as a whole.

Defendant further submits that the use of headings throughout the Master Complaint is improper and, therefore, no response to them is required. To the extent a response is required,

and to the extent that such headings contain allegations directed toward Defendants, Defendant denies those allegations.

INTRODUCTION

1. Defendant admits that Plaintiffs bring this Master Complaint against Defendants for equitable, injunctive, and declaratory relief and monetary restitution and/or damages. Defendant denies that Plaintiffs' attempt to collectively refer to the separate entities named in Paragraph 1 as "Guidant" is correct, appropriate or has any legal significance whatsoever relative to Plaintiffs' claims and Plaintiffs' ability to seek relief or recover damages against the individual Defendants and denies that Plaintiffs are entitled to recover any relief whatsoever.

2. Defendant admits the allegations of Paragraph 2.

SUMMARY OF GUIDANT MISCONDUCT AND RESULTING DANGERS, DAMAGES, INJURIES, AND CLAIMS

3. Defendant admits that this Master Complaint is filed on behalf of Plaintiffs presently in this MDL. Defendant denies the remaining allegations of Paragraph 3.

4. Defendant admits that in April 2006, Guidant Corporation's shareholders approved its acquisition by Boston Scientific Corporation ("Boston Scientific") and that on April 21, 2006, Boston Scientific's acquisition of Guidant Corporation was completed. Defendant denies the remaining allegations of Paragraph 4.

5. Defendant denies the allegations of Paragraph 5.

6. Defendant admits that the Master Complaint sets forth claims sounded in tort, contract, consumer and business protection statutes and equity but denies that Plaintiffs are entitled to any relief whatsoever. Defendant denies the remaining allegations of Paragraph 6.

7. Defendant admits that the Master Complaint sets forth the claims enumerated in Paragraph 7 but denies that Plaintiffs are entitled to any relief whatsoever.

8. Defendant denies the allegations of Paragraph 8.

9. Defendant admits that this Master Complaint includes claims of third-party persons such as health and welfare funds, self insured employers, and non-profit and for profit health insurers, but states that these claims were dismissed by an Order of the Court dated April 16, 2007. Defendant denies the remaining allegations of Paragraph 9.

10. Defendant denies the allegations of Paragraph 10.

11. Defendant states that it has always treated patients and their medical professionals with forthrightness, respect, and candor. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11 and, therefore, denies the same.

12. Defendant admits that Paragraph 12 of the Master Complaint purports to set forth a table of contents for the Master Complaint.

PARTIES

Device Recipient Plaintiffs

13. Defendant admits upon information and belief that on or about April 10, 2003, Plaintiff John Boland was implanted with a CONTAK RENEWAL Model H135 cardiac resynchronization therapy defibrillator ("CRT-D"). Defendant further admits upon information and belief that on or about June 27, 2005, Plaintiff John Boland's CONTAK RENEWAL Model H135 CRT-D was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 13. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 13 and, therefore, denies the same.

14. Defendant admits upon information and belief that on or about April 11, 2001, Decedent John Brennan was implanted with a VENTAK PRIZM 2 DR Model 1861 implantable cardioverter defibrillator (“ICD”). Defendant denies that it is liable for the injuries or damages alleged in Paragraph 14. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 14 and, therefore, denies the same.

15. Defendant admits upon information and belief that on or about April 26, 2002, Plaintiff Christofer Brewster was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that on or about July 12, 2005, Plaintiff Christofer Brewster’s VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 15. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15 and, therefore, denies the same.

16. Defendant admits upon information and belief that in or around December 2002, Plaintiff Eugene Clasby was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant states upon information and belief that on or about May 4, 2006, Plaintiff Eugene Clasby’s VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 16. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 16 and, therefore, denies the same.

17. Defendant admits upon information and belief that on or about June 16, 1999, Plaintiff Paul Jones was implanted with a DISCOVERY DDDRO Model 1273 pacemaker. Defendant further admits upon information and belief that on or about August 8, 2005, Plaintiff Paul Jones’ DISCOVERY DDDRO Model 1273 pacemaker was explanted and replaced.

Defendant denies that it is liable for the injuries or damages alleged in Paragraph 17. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 17 and, therefore, denies the same.

18. Defendant admits upon information and belief that on or about July 15, 2003, Plaintiff Zina Lewis was implanted with an INSIGNIA Plus DR Model 1297 pacemaker. Defendant further admits upon information and belief that on or about November 22, 2005, Plaintiff Zina Lewis' INSIGNIA Plus DR Model 1297 pacemaker was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 18. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 18 and, therefore, denies the same.

19. Defendant admits upon information and belief that on or about February 1, 2005, Plaintiff Judy Passante was implanted with a CONTAK RENEWAL 3 Model H170 CRT-D. Defendant further admits upon information and belief that on or about December 7, 2005, Plaintiff Judy Passante's CONTAK RENEWAL 3 Model H170 CRT-D was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 19. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 19 and, therefore, denies the same.

20. Defendant admits upon information and belief that on or about March 22, 2005, Plaintiff Mati Peleg was implanted with a VITALITY AVT Model A155 ICD. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 20. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 20 and, therefore, denies the same.

21. Defendant admits upon information and belief that on or about January 30, 2004, Decedent Marvin Schacher was implanted with a CONTAK RENEWAL Model H177 CRT-D. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 21. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 21 and, therefore, denies the same.

22. Defendant admits upon information and belief that on or about November 3, 2003, Plaintiff Thomas Shreiner was implanted with a VITALITY AVT Model A135 ICD. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 22. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 22 and, therefore, denies the same.

23. Defendant admits upon information and belief that on or about August 31, 2001, Plaintiff Heather Sorensen was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that on or about November 28, 2005, Plaintiff Heather Sorensen's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 23. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23 and, therefore, denies the same.

24. Defendant admits upon information and belief that on or about October 3, 2002, Plaintiff Oren Urich was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 24. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24 and, therefore, denies the same.

25. Defendant admits upon information and belief that in or around November 2002, Plaintiff Edith Walker was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that in or around September 2005, Plaintiff Edith Walker's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 25. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 25 and, therefore, denies the same.

26. Defendant admits upon information and belief that on or about June 29, 2001, Plaintiff Larry Wenig was implanted with a VENTAK PRIZM 2 DR Model 1861 ICD. Defendant further admits upon information and belief that on or about August 3, 2005, Plaintiff Larry Wenig's VENTAK PRIZM 2 DR Model 1861 ICD was explanted and replaced. Defendant denies that it is liable for the injuries or damages alleged in Paragraph 26. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26 and, therefore, denies the same.

TPP Plaintiffs

27. Defendant states that the claims brought by Plaintiff UCFW Fund were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 27.

28. Defendant states that the claims brought by Plaintiff City of Bethlehem, Pennsylvania were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 28.

29. Defendant states that the claims brought by the self-styled “TPP Plaintiffs” were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 29.

MSP Plaintiff

30. Defendant states that the Medicare Secondary Payor Act (“MSP”) claims brought by Plaintiff Tamela Ivens were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 30.

Plaintiff Appearance In and Purpose Regarding the Master Complaint

31. Defendant generally admits that all the named Plaintiffs in the Master Complaint purport to bring this action in their individual and/or representative capacities on their own behalf or on behalf of all others similarly situated in order to obtain the relief sought herein, but denies that Plaintiffs are entitled to any such relief and denies that the named Plaintiffs have standing to assert claims on behalf of all others similarly situated. Defendant denies that class treatment is appropriate in this action and reserves the right to object to any individual who Plaintiffs may purport to offer as an appropriate class representative. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31 and, therefore, denies the same.

32. Defendant denies that Plaintiffs have standing to bring this lawsuit “as a public benefit action,” denies that this lawsuit will bring any “public benefit,” denies that Plaintiffs are entitled to any relief whatsoever, and denies the remaining allegations of Paragraph 32.

Defendants

33. Defendant admits that Guidant Corporation is an Indiana corporation with its principal place of business at 111 Monument Circle, Indianapolis Indiana. Defendant further

admits that the development, manufacture, and sale of ICDs, CRT-Ds, and pacemakers by direct and indirect subsidiaries of Guidant Corporation is collectively referred to as Cardiac Rhythm Management (“CRM”), and that CRM operations are principally conducted at 4100 Hamline Avenue North, St. Paul, Minnesota. Defendant denies that Guidant Corporation develops, researches, advertises, promotes, markets, or sells ICDs, or any devices, and denies the remaining allegations of Paragraph 33.

34. Defendant admits that it is an Indiana Corporation with its principal place of business at 111 Monument Circle, Indianapolis, Indiana. Defendant further admits that it markets and sells ICDs and pacemakers manufactured by Cardiac Pacemakers, Inc. (“CPI”). Defendant states that it is a wholly-owned subsidiary of CPI. Defendant denies the remaining allegations of Paragraph 34.

35. Defendant admits that CPI is a Minnesota corporation with its principal place of business at 4100 Hamline Avenue North, St. Paul, Minnesota. Defendant further admits that CPI develops ICDs and pacemakers and that CPI is a wholly-owned subsidiary of Guidant Corporation. Defendant denies the remaining allegations of Paragraph 35.

36. Defendant admits that Boston Scientific is a Delaware corporation with its principal place of business in Natick, Massachusetts. Defendant further admits that in January 2006, Boston Scientific entered into an agreement to acquire Guidant Corporation and its subsidiaries for approximately \$27 billion. Defendant admits that the first sentence of Paragraph 36 purports to quote and/or characterize information found on Boston Scientific’s Internet website. Defendant states that the complete and precise content of that information can be ascertained from the website itself. Defendant denies the remaining allegations of Paragraph 36.

JURISDICTION AND VENUE

37. Defendant admits the allegations of Paragraph 37.

38. Defendant admits that venue is proper in this District. Defendant further admits that CPI has its principal place of business in this District. Defendant denies the remaining allegations of Paragraph 38.

FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

I. GUIDANT CORPORATE STRUCTURE

39. Defendant admits that CPI designs and manufacturers and that GSC markets and sells the cardiac medical devices at issue in this Master Complaint. Defendant denies the remaining allegations of Paragraph 39.

40. Defendant admits that GSC markets and sells the cardiac medical devices at issue in this Master Complaint. Defendant states that GSC is a wholly-owned subsidiary of CPI, which in turn is a wholly-owned subsidiary of Guidant Corporation. Defendant denies the remaining allegations of Paragraph 40.

41. Defendant admits that the allegations contained in the second sentence of Paragraph 41 purport to quote, characterize, and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant admits that GSC's marketing materials utilize the Guidant logo. Defendant denies the remaining allegations of Paragraph 41.

42. Defendant admits that Guidant Corporation's subsidiaries have their own officers. Defendant denies the remaining allegations of Paragraph 42.

43. Defendant admits that CPI's products include ICDs, pacemakers, and lead systems. Defendant generally admits the allegations in the second and third sentences of Paragraph 43. Defendant denies the remaining allegations of Paragraph 43.

44. Defendant admits that the allegations contained in the first sentence of Paragraph 44 purport to quote, characterize, and/or paraphrase the Corporate Overview Page at www.Guidant.com. Defendant states that the complete and precise content of that Internet web page can be ascertained from the website itself. Defendant generally admits the allegations in the second and third sentences of Paragraph 44. Defendant states that the referenced financial information is publicly available and denies that the allegations of Paragraph 44 fairly or completely characterize that financial information.

II. OVERVIEW OF IMPLANTABLE DEVICES FOR CARDIAC RHYTHM MANAGEMENT

45. Defendant generally admits the allegations of Paragraph 45.

46. Defendant generally admits the allegations of Paragraph 46.

47. Defendant admits that the ICDs designed and manufactured by CPI and marketed and sold by GSC include the three components identified in Paragraph 47 of the Master Complaint. Defendant further states that ICDs are complex devices that contain many components and denies that the allegations of Paragraph 47 provide a complete or accurate representation of the components in an ICD.

48. Defendant generally admits the allegations of Paragraph 48.

49. Defendant generally admits the allegations of Paragraph 49.

50. Defendant states that, today, most defibrillators actually include both pacemaker and defibrillator functions. Defendant generally admits the remaining allegations of Paragraph 50.

51. Defendant generally admits the allegations of Paragraph 51 but states that a patient with an abnormal heart rate may be at risk of injury or death regardless of whether the patient's ICD or pacemaker delivers appropriate therapy.

52. Defendant admits that ICDs are intended to administer potentially life-saving therapy to patients with serious underlying heart conditions. Defendant further states that a patient's underlying heart condition can lead to death regardless of whether the patient's ICD delivers appropriate therapy.

53. Defendant generally admits the allegations of Paragraph 53.

54. Defendant generally admits the allegations of Paragraph 54.

55. Defendant generally admits the allegations of Paragraph 55. Defendant further states that a patient's underlying heart condition can lead to death regardless of whether the patient's pacemaker provides appropriate pacing.

56. Defendant denies the allegations of Paragraph 56.

III. DEVICES AT ISSUE

57. Defendant denies that Plaintiffs are entitled to any relief whatsoever.

58. Defendant denies that individuals who have been implanted with the ICDs and CRT-Ds described in Paragraph 58 are entitled to any relief whatsoever.

59. Defendant denies that individuals who have been implanted with the pacemakers described in Paragraph 59 are entitled to any relief whatsoever.

60. Paragraph 60 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that CPI has complied with all approval conditions pertaining to cardiac medical devices and denies the allegations of Paragraph 60.

61. Defendant denies that it has removed devices from the market. Defendant admits that certain communications to physicians involving the devices at issue have been classified as Class I or Class II recalls by the FDA.

62. Defendant admits that the allegations contained in paragraph 62 of Plaintiffs' Master Complaint purport to reference, interpret, and/or paraphrase a section of the Code of Federal Regulations ("C.F.R."). Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

63. Defendant admits that the allegations of Paragraph 63 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

64. Defendant admits that the allegations of Paragraph 64 purport to reference, interpret, and/or paraphrase a section of the United States Code ("U.S.C."). Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

65. Defendant admits that the allegations of Paragraph 65 purport to reference, interpret, and/or paraphrase a section of the U.S.C. Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

66. Defendant admits that the allegations of Paragraph 66 purport to reference, interpret, and/or paraphrase a section of the U.S.C. Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

67. Defendant admits that the allegations of Paragraph 67 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

68. Defendant admits that the allegations of Paragraph 68 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

69. Defendant admits that the allegations of Paragraph 69 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

70. Defendant admits that the allegations of Paragraph 70 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

71. Defendant admits that the allegations of Paragraph 71 purport to reference, interpret, and/or paraphrase a section of the C.F.R. Defendant states that the complete and precise content of the regulation can be ascertained from the regulation itself.

72. Paragraph 72 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that the allegations of Paragraph 72 purport to reference, interpret, and/or paraphrase certain FDA regulations. Defendant states that the complete and precise content of these regulations can be ascertained from the regulations themselves.

73. Defendant admits that the allegations of Paragraph 73 purport to reference, interpret, and/or paraphrase a July 18, 2002 approval letter and a section of the C.F.R. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves.

74. Defendant denies the allegations of Paragraph 74.

IV. HISTORY OF THE DEVICES

A. Summary

75. Defendant admits that CPI manufactured and that GSC promoted, sold, and distributed the devices at issue in this litigation. Defendant denies the remaining allegations of Paragraph 75.

76. Defendant denies the allegations of Paragraph 76.

77. Defendant denies the allegations of Paragraph 77.

78. Defendant admits that the allegations of Paragraph 78 purport to quote, characterize, and/or paraphrase a May 24, 2006 *New York Times* article. Defendant states that the complete and precise content of that article can be ascertained from the article itself. Defendant denies Plaintiffs' characterization of the article and denies the remaining allegations of Paragraph 78.

79. Defendant generally admits that the May 24, 2006 *New York Times* article referenced in Paragraph 79 attracted attention. Defendant denies the remaining allegations of Paragraph 79.

80. Defendant admits that CPI has issued several "Dear Doctor" and "Dear Patient" letters in order to provide current and accurate information to doctors and patients as this information is learned by CPI. Defendant denies that the information in these letters has been inconsistent, unclear, or incomplete. Defendant generally admits that some of its recommendations have evolved over time as new information is learned. Defendant denies that device recipients and their medical advisors, as a group, remain confused and unclear as to the risks of the devices and the appropriate course of action to take. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 80 and, therefore, denies the same.

81. Defendant denies the allegations of Paragraph 81.

82. Defendant denies the allegations of Paragraph 82.

83. Defendant denies the allegations of Paragraph 83.

B. Ventak Prizm ICDs

84. Defendant denies the allegations of Paragraph 84.

85. Defendant denies the allegations of Paragraph 85..

86. Defendant admits that CPI first submitted the VENTAK PRIZM for approval in August 1996 pursuant to PMA P960040, and that Models 1810 and 1815 were originally approved for sale on July 18, 1997. Defendant further admits that the first implantation of the VENTAK PRIZM was announced on January 27, 1999. Defendant denies the remaining allegations of Paragraph 86.

87. Defendant admits that CPI sought approval of the VENTAK PRIZM 2 VR Model 1860 and VENTAK PRIZM 2 DR Model 1861 pursuant to PMA Supplement P960040 S015, and that it received notice of the approval of this PMA Supplement in August 2000. Defendant admits that GSC began selling the VENTAK PRIZM 2 DR Model 1861 in 2000. Defendant denies the remaining allegation of Paragraph 87.

88. Defendant admits the allegations of Paragraph 88.

89. Defendant admits that Paragraph 89 purports to quote, characterize, and/or paraphrase a May 25, 2005 press release and a June 14, 2005 *New York Times* article. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of these documents and denies the remaining allegations of Paragraph 89.

90. Defendant denies the allegations of Paragraph 90.

91. Defendant denies the allegations of Paragraph 91.

92. Defendant admits that explantation of an ICD involves a surgical procedure and that surgery involves certain risks including scarring. Defendant admits that ICDs are connected to the heart tissue with lead wires but denies that those lead wires need to be replaced in a typical explant surgery or that the presence of those lead wires appreciably increases the risks attendant to explant surgery.

93. Defendant denies the allegations of Paragraph 93.

94. Defendant admits that on May 20, 2002, following the third observed instance of arcing between the feedthrough wire and the backfill tube in a VENTAK PRIZM 2 DR Model 1861 ICD, CPI opened a “trend” to further investigate the instances of arcing. Defendant denies the remaining allegations of Paragraph 94.

95. Defendant admits that in April 2002, CPI made a manufacturing change to the VENTAK PRIZM 2 DR Model 1861. The change was intended to prevent the occurrence of arcing between the feedthrough wire and the backfill tube by ensuring appropriate spacing between the feedthrough wire and the backfill tube. The change involved placing medical adhesive between the feedthrough wire and backfill tube and allowing that medical adhesive to cure before proceeding with the remaining manufacturing steps. Defendant states that CPI complied with all FDA regulations pertaining to this manufacturing change. Defendant denies the remaining allegations of Paragraph 95.

96. Defendant admits that in November 2002, CPI made a manufacturing change to the VENTAK PRIZM 2 DR Model 1861. This change involved adding polyimide insulation to the backfill tube. Defendant states that CPI complied with all FDA regulations pertaining to this manufacturing change. Defendant denies the remaining allegations of Paragraph 96.

97. Defendant admits that the allegations of Paragraph 97 purport to quote, characterize, and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of this report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of this report and denies the remaining allegations of Paragraph 97.

98. Defendant admits that the allegations of Paragraph 98 purport to quote, characterize, and/or paraphrase a June 2, 2005 *New York Times* article and a May 24, 2005 *New York Times* article. Defendant states that the complete and precise content of these articles can be ascertained from the articles themselves. Defendant denies Plaintiffs' characterization of these articles and denies the remaining allegations of Paragraph 98.

99. Defendant admits that the trend report on the VENTAK PRIZM 2 DR Model 1861 was closed in April 2003. Defendant denies the remaining allegations of Paragraph 99.

100. Defendant admits that after April 2002, CPI continued to receive occasional reports of additional instances of arcing between the feedthrough wire and the backfill tube. Defendant admits that by February 2005 there had been 25 reported events of arcing between the feedthrough wire and the backfill tube. Defendant denies the remaining allegations of Paragraph 100.

101. Defendant admits that on March 14, 2005, a 21 year-old college student from Minnesota with hypertrophic cardiomyopathy, who had been implanted with a VENTAK PRIZM 2 DR 1861 ICD, collapsed and died. Defendant is without knowledge or information sufficient to admit or deny the allegations regarding the cause of death referred to in Paragraph 101 and, therefore, denies the same.

102. Defendant admits that physicians at the Minneapolis Heart Institute Foundation explanted the individual device referred to in Paragraph 102 and sent it to CPI for analysis.

Defendant further admits that analysis confirmed that the device exhibited signs of arcing indicative of a short between the feedthrough wire and the backfill tube. Defendant further admits that the device had been disabled and that its memory was destroyed. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 102 and, therefore, denies the same.

103. Defendant is without knowledge of information sufficient to form a belief as to the truth of the allegations of the first sentence of Paragraph 103 and, therefore, denies the same. Defendant admits that representatives of CPI met with physicians from the Minneapolis Heart Institute Foundation on May 12, 2005. Defendant denies Plaintiffs' characterization of the meeting and denies the remaining allegations of Paragraph 103.

104. Defendant admits that Paragraph 104 refers to and purports to characterize and/or paraphrase a May 23, 2005 letter to physicians. Defendant denies Plaintiffs' characterization of this letter and denies the remaining allegations of Paragraph 104.

105. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 105 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 105. To the extent a response is required, Defendant admits that Guidant Corporation's Chief Medical and Technology Officer sold company stock but denies Plaintiffs' characterization of, and implication regarding the meaning of, such sales of stock. Defendant denies the remaining allegations of Paragraph 105.

106. Defendant admits that Paragraph 106 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and

precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 106.

107. Defendant admits that Paragraph 107 refers to and purports to selectively quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 107.

108. Defendant denies the allegations of Paragraph 108.

109. Defendant admits that CPI instituted a manufacturing change to replace polyimide insulation in the VENTAK PRIZM 2 DR Model 1861 with PEEK insulation because of rare instances of degrading of the polyimide insulation. Defendant denies the remaining allegations of Paragraph 109.

110. Defendant admits that CPI applied for and received FDA approval for the substitution of polyimide insulation with PEEK insulation. Defendant admits that the allegations of the second sentence of Paragraph 110 refer to and purport to quote, characterize, and/or paraphrase an October 13, 2005 FDA Notification. Defendant states that the complete and precise content of that notification can be ascertained from the notification itself. Defendant denies the remaining allegations of Paragraph 110.

111. Defendant admits that Paragraph 111 refers to and purports to quote, characterize, and/or paraphrase a May 25, 2005 press release. Defendant states that the complete and precise content of that press release can be ascertained from the press release itself. Defendant denies the remaining allegations of Paragraph 111.

112. Defendant admits that Paragraph 112 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 112.

113. Defendant admits that Paragraph 113 refers to and purports to quote, characterize, and/or paraphrase a July 1, 2005 FDA press release. Defendant states that the complete and precise content of that press release can be ascertained from the press release itself.

114. Defendant admits that Paragraph 114 refers to and purports to quote, characterize, and/or paraphrase an FDA report and a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of these documents and denies the remaining allegations of Paragraph 114.

115. Defendant denies the allegations of Paragraph 115.

C. Contak Renewal 1 and 2

116. Defendant admits that CPI manufactured the CONTAK RENEWAL Model H135 and the CONTAK RENEWAL 2 Model H155 CRT-Ds. Defendant denies the remaining allegations of Paragraph 116.

117. Defendant denies the allegations of Paragraph 117.

118. Defendant admits that Paragraph 118 purports to characterize and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 118.

119. Defendant denies the allegations of Paragraph 119.

120. Defendant denies the allegations of Paragraph 120.

121. Defendant admits that Paragraph 121 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 121.

122. Defendant admits that Paragraph 122 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 122.

123. Defendant admits that Paragraph 123 purports to characterize and/or paraphrase a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of that document can be ascertained from the document itself. Defendant denies Plaintiffs' characterization of the document and denies the remaining allegations of Paragraph 123.

124. Defendant admits that Paragraph 124 purports to characterize and/or paraphrase a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of that document can be ascertained from the document itself. Defendant denies Plaintiffs' characterization of the document and denies the remaining allegations of Paragraph 124.

125. Defendant admits that Paragraph 125 refers to and purports to quote, characterize, and/or paraphrase a June 17, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

126. Defendant denies the allegations of Paragraph 126.

127. Defendant admits that Paragraph 127 refers to and purports to characterize and/or paraphrase a June 17, 2005 letter and a September 12, 2005 letter. Defendant states that the complete and precise content of these letters can be ascertained from the letters themselves.

128. Defendant admits that Paragraph 128 refers to and purports to characterize and/or paraphrase a December 20, 2005 Advisory Update. Defendant states that the complete and precise content of that document can be ascertained from the document itself.

129. Defendant admits that Paragraph 129 purports to characterize and/or paraphrase an FDA recall notice. Defendant states that the complete and precise content of that notice can be ascertained from the notice itself.

130. Defendant admits that CPI learned of rare instances where the polyimide insulation in the CONTAK RENEWAL Model H135 and CONTAK RENEWAL 2 Model H155 degraded. Defendant denies that the rare instances of degrading observed in the polyimide insulation could, by themselves, result in short circuiting of the device. Defendant denies the remaining allegations of Paragraph 130.

131. Defendant denies the allegations of Paragraph 131.

132. Defendant admits that Paragraph 132 refers to and purports to quote, characterize, and/or paraphrase a December 2005 FDA report. Defendant states that the complete and precise content of that report can be ascertained from the report itself

133. Defendant denies the allegations of Paragraph 133.

D. Contak Renewal 3 and 4

134. Defendant admits that CPI manufactured the devices referenced in Paragraph 134.

135. Defendant denies the allegations of Paragraph 135.

136. Defendant admits that Paragraph 136 refers to and purports to quote, characterize, and/or paraphrase a June 23, 2005 letter to physicians and a June 30, 2005 FDA recall notice. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of these documents and denies the remaining allegations of Paragraph 136.

137. Defendant denies the allegations of Paragraph 137.

E. Ventak Prizm AVT, Vitality AVT, and Renewal AVT

138. Defendant admits that CPI manufactured the devices referenced in Paragraph 138. Defendant denies that the devices were "potentially defective" and denies the remaining allegations of Paragraph 138.

139. Defendant denies the allegations of Paragraph 139.

140. Defendant admits that Paragraph 140 refers to and purports to quote, characterize, and/or paraphrase June 17, 2005 and July 22, 2005 letters to physicians. Defendant states that the complete and precise content of these letters can be ascertained from the letters themselves. Defendant denies Plaintiffs' characterization of the letters and denies the remaining allegations of Paragraph 140.

141. Defendant admits that Paragraph 141 refers to and purports to quote, characterize, and/or paraphrase a July 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 141.

142. Defendant admits that Paragraph 142 refers to and purports to characterize and/or paraphrase a January 2006 statement from CPI. Defendant states that the complete and precise

content of that statement can be ascertained from the statement itself. Defendant admits the allegations of the second sentence of Paragraph 142.

143. Defendant denies the allegations of Paragraph 143.

144. Defendant admits that Paragraph 144 refers to and purports to characterize and/or paraphrase an August 12, 2005 FDA recall notice. Defendant states that the complete and precise content of this notice can be ascertained from the notice itself.

145. Defendant denies the allegations of Paragraph 145.

F. Discovery, Pulsar, Meridian, Virtus, and Intelis Pacemakers

146. Defendant admits that CPI manufactures the pacemakers referenced in Paragraph 146.

147. Defendant denies the allegations of Paragraph 147.

148. Defendant admits that Paragraph 148 purport to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 148.

149. Defendant denies the allegations of Paragraph 149.

150. Defendant admits that Paragraph 150 refers to and purports to quote, characterize, and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 150.

151. Defendant admits that Paragraph 151 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise

content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 151.

152. Defendant admits that Paragraph 152 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 152.

153. Defendant admits that Paragraph 153 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians and a July 19, 1005 *New York Times* article. Defendant states that the complete and precise content of these documents can be ascertained from the documents themselves. Defendant denies Plaintiffs' characterization of the documents and denies the remaining allegations of Paragraph 153.

154. Defendant admits that Paragraph 154 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

155. Defendant denies the allegations of Paragraph 155.

156. Defendant admits that Paragraph 156 refers to and purports to characterize and/or paraphrase a July 18, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

157. Defendant admits that Paragraph 157 refers to and purports characterize and/or paraphrase an FDA recall notice. Defendant states that the complete and precise content of the notice can be ascertained from the notice itself.

158. Defendant admits that Paragraph 158 refers to and purports to characterize and/or paraphrase a January 23, 2006 letter to physicians. Defendant states that the complete and

precise content of this letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 158.

159. Defendant denies the allegations of Paragraph 159.

G. Insignia and Nexus Pacemakers

160. Defendant denies the allegations of Paragraph 160.

161. Defendant denies the allegations of Paragraph 161.

162. Defendant denies the allegations of Paragraph 162.

163. Defendant admits that Paragraph 163 refers to and purports to quote, characterize, and/or paraphrase a September 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

164. Defendant admits that Paragraph 164 refers to and purports to characterize and/or paraphrase a September 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 164.

165. Defendant admits that Paragraph 165 refers to and purports to characterize and/or paraphrase a September 22, 2005 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 165.

166. Defendant admits that Paragraph 166 refers to and purports to characterize and/or paraphrase an FDA recall notice. Defendant states that the complete and precise content of that notice can be ascertained from the notice itself.

167. Defendant denies the allegations of Paragraph 167.

H. Pending Recalls

168. Defendant admits that CPI continues to follow all FDA guidelines and communicate product information to doctors and patients as necessary. Defendant admits that the remaining allegations of Paragraph 168 refer to and purport to quote, characterize, and/or paraphrase a March 11, 2006 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 168.

169. Defendant admits that Paragraph 169 refers to and purports to quote, characterize, and/or paraphrase a March 11, 2006 letter to physicians. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself.

V. GUIDANT'S PAST AND PRESENT ILLEGAL AND REPREHENSIBLE CONDUCT

A. Guidant's Failure to Meet Basic Manufacturing & Regulatory Standards

170. Defendant admits that the FDA conducted an inspection of CPI's facilities during August 22, 2005 to September 1, 2005. Defendant further admits that at the conclusion of the inspection the FDA issued a 483 Inspection Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant denies the remaining allegations of Paragraph 170.

171. Defendant admits that Paragraph 171 refers to and purports to quote and/or characterize a February 8, 2006 FDA 483 Inspection Report. Defendant states that the complete and precise content of that report and be ascertained from the report itself.

172. Defendant admits that Paragraph 172 refers to and purports to quote, characterize, and/or paraphrase a February 8, 2006 FDA 483 Inspection Report. Defendant states that the complete and precise content of that report and be ascertained from the report itself. Defendant

denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 172.

173. Defendant denies the allegations of Paragraph 173.

174. Defendant admits that Paragraph 174 refers to and purports to quote, characterize, and/or paraphrase a February 8, 2006 FDA 483 Inspection Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 174.

175. Defendant admits that Paragraph 175 purports to characterize and/or paraphrase February 8, 2006 and September 1, 2005 FDA 483 Inspection Reports. Defendant states that the complete and precise content of these reports can be ascertained from the reports themselves. Defendant denies the remaining allegations of Paragraph 175.

176. Defendant denies the allegations of Paragraph 176.

177. Defendant denies the allegations of Paragraph 177.

178. Paragraph 178 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 178

179. Defendant denies the allegations of Paragraph 179.

B. Guidant's Concealment of the Device Defects

180. Defendant denies the allegations of Paragraph 180.

181. Defendant denies the allegations of Paragraph 181.

182. Defendant denies the allegations of Paragraph 182.

183. Defendant denies the allegations of Paragraph 183.

184. Defendant denies the allegations of Paragraph 184.

185. Defendant admits that CPI regularly issues Product Performance Reports. Defendant denies the remaining allegations of Paragraph 185.

186. Defendant denies the allegations of Paragraph 186.

187. Defendant denies the allegations of Paragraph 187.

188. Defendant denies the allegations of Paragraph 188.

189. Defendant denies the allegations of Paragraph 189.

190. Defendant denies the allegations of Paragraph 190.

191. Defendant denies the allegations of Paragraph 191.

192. Defendant denies the allegations of Paragraph 192.

193. Defendant admits that Paragraph 193 refers to and purports to quote, characterize, and/or paraphrase a June 24, 2005 letter from Allan Gorsett. Defendant states that the complete and precise content of that letter can be ascertained from the letter itself. Defendant denies Plaintiffs' characterization of the letter and denies the remaining allegations of Paragraph 193.

194. Defendant admits that Paragraph 194 purports to characterize and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of the report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 194.

C. Guidant's Deceptive Promotional and Marketing Activities

195. Defendant denies the allegations of Paragraph 195.

196. Defendant admits that Paragraph 196 refers to and purports to depict an advertisement for an ICD. Defendant states that the complete and precise content of the advertisement can be ascertained from the advertisement itself. Defendant denies Plaintiffs' attempt to mischaracterize the advertisement or to take portions of it out of context.

197. Defendant admits that Paragraph 197 refers to and purports to depict and characterize an advertisement for an ICD. Defendant states that the complete and precise content of the advertisement can be ascertained from the advertisement itself. Defendant denies Plaintiffs' attempt to mischaracterize the advertisement or to take portions of it out of context. Defendant denies the remaining allegations of Paragraph 197.

D. Guidant's Continued Failure to Provide Adequate and Accurate Information

198. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 198 and, therefore, denies the same.

199. Defendant denies the allegations of Paragraph 199.

200. Defendant denies the allegations of Paragraph 200.

201. Defendant admits that some of the allegations of Paragraph 201 purport to characterize and/or paraphrase communications issued by CPI. Defendant states that the complete and precise content of these communications can be ascertained from the communications themselves. Defendant denies Plaintiffs' characterization of these communications and denies the remaining allegations of Paragraph 201.

202. Defendant admits that Paragraph 202 purports to characterize and/or paraphrase unidentified "FDA estimates." Defendant states that the complete and precise content of these "FDA estimates" can be ascertained from any such documents themselves. Defendant denies Plaintiffs' characterization of the documents and denies the remaining allegations of Paragraph 202.

203. Defendant admits that Paragraph 203 refers to and purports to quote, characterize and/or paraphrase June 17, 2005 and December 20, 2005 letters to physicians. Defendant states that the complete and precise content of these letters can be ascertained from the letters

themselves. Defendant denies Plaintiffs' characterization of these letters and denies the remaining allegations of Paragraph 203.

E. Guidant's History of Criminal Misconduct

204. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 204 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 204. To the extent a response is required, Defendant admits that Paragraph 204 refers to and purports to quote, characterize, and/or paraphrase a plea agreement entered into by a separate and distinct corporate entity that is not a party to this lawsuit, Endovascular Technologies, Inc. Defendant states that the complete and precise content of the plea agreement can be ascertained from the agreement itself.

205. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 205 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 205. To the extent a response is required, Defendant denies the allegations of Paragraph 205.

206. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 206 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 206. To the extent a response is required, Defendant admits that Paragraph 206 refers to and purports to quote, characterize, and/or paraphrase a Corporate Integrity Agreement. Defendant states that the complete and precise content of this agreement can be

ascertained from the agreement itself. Defendant denies Plaintiffs' characterization of the agreement and denies the remaining allegations of Paragraph 206.

207. Pursuant to Federal Rule of Civil Procedure 12(f), Defendant moves to strike Paragraph 207 of the Master Complaint as "immaterial, impertinent, or scandalous matter" which is included solely for the purpose of harassment. Therefore, Defendant should not be required to respond to Paragraph 207. To the extent a response is required, Defendant denies the allegations of Paragraph 207.

208. Defendant denies the allegations of Paragraph 208.

209. Defendant admits that Paragraph 209 purports to characterize and/or paraphrase an Independent Panel Report. Defendant states that the complete and precise content of that report can be ascertained from the report itself. Defendant denies Plaintiffs' characterization of the report and denies the remaining allegations of Paragraph 209.

210. Defendant admits that Paragraph 210 refers to and purports to characterize and/or paraphrase a June 16, 2005 *Minneapolis Star-Tribune* article. Defendant states that the complete and precise content of that article can be ascertained from the article itself. Defendant denies Plaintiffs' characterization of that article and denies the remaining allegations of Paragraph 210.

211. Defendant denies the allegations of Paragraph 211.

F. The Guidant Co-Defendants Are Agents and Alter Egos of One Another

212. Paragraph 212 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 212.

213. Paragraph 213 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 213.

214. Paragraph 214 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that CPI designed and manufactured and that GSC marketed and sold the cardiac medical devices at issue in this litigation. Defendant denies the remaining allegations of Paragraph 214.

215. Defendant denies the allegations of Paragraph 215.

216. Defendant denies the allegations of Paragraph 216.

217. Defendant admits that Boston Scientific has acquired Guidant Corporation. Defendant denies the remaining allegations of Paragraph 217.

VI. THE MEDICARE AS SECONDARY PAYER STATUTE

218. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 218.

219. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 219.

220. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 220.

221. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 221.

222. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 222.

223. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 223.

224. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 224.

225. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 225.

226. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 226.

227. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 227.

228. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 228.

229. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 229.

230. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 230.

231. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 231.

232. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 232.

233. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 233.

234. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 234.

235. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 235.

236. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 236.

237. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 237.

238. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 238.

239. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 239.

240. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 240.

241. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 241.

242. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 242.

243. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 243.

244. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 244.

245. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 245.

246. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 246.

247. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 247.

248. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 248.

249. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 249.

250. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 250.

251. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 251.

252. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 252.

253. Defendant states that the claims of the Master Complaint brought pursuant to the Medicare as Secondary Payor statute were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 253.

CLASS ACTION ALLEGATIONS

254. Defendant admits that Plaintiffs seek to bring this case on behalf of at least two proposed classes but denies that class treatment is appropriate in this case and denies that the proposed classes defined in Paragraph 254 of the Master Complaint are appropriate classes.

255. Defendant admits that Plaintiffs will seek class treatment for certain groups of Plaintiffs but denies that class treatment is appropriate in this case.

256. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 256 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

257. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 257 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

258. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 258 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

259. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 259 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

260. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 260 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

261. Defendant admits that Plaintiffs seek class treatment for the subclass purported to be defined by the allegations of Paragraph 261 but denies that the allegations set forth an appropriate subclass and denies that class treatment is appropriate for the proposed subclass.

262. Paragraph 262 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 262.

263. Paragraph 263 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 263.

264. Paragraph 264 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 264.

265. Paragraph 265 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 265.

266. Paragraph 266 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 266.

267. Paragraph 267 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 267.

268. Paragraph 268 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 268.

269. Paragraph 269 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 269.

CLAIMS FOR RELIEF
DEVICE RECIPIENT PLAINTIFFS

270. Defendant denies that the Device Recipient Plaintiffs are entitled to any relief whatsoever.

COUNT I
STRICT LIABILITY – FAILURE TO WARN

271. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 270 as if fully set forth herein.

272. Defendant admits that CPI designed and manufactured and that GSC marketed and sold cardiac medical devices and that CPI and GSC were aware that the devices would be implanted in patients who suffered from the heart conditions for which the devices were indicated. Defendant denies the remaining allegations of Paragraph 272.

273. Defendant admits that the devices were expected to reach Plaintiffs' treating physicians without substantial change in their condition. Defendant is without knowledge or information sufficient to admit or deny that the devices reached Plaintiffs without substantial

change in their condition as manufactured and sold. Defendant denies the remaining allegations of Paragraph 273.

274. Defendant denies the allegations of Paragraph 274.

275. Defendant is without knowledge or information sufficient to admit or deny that the devices were implanted and used in the manner for which they were intended and, therefore, denies the same. Defendant denies the remaining allegations of Paragraph 275.

276. Defendant denies the allegations of Paragraph 276.

277. Defendant denies the allegations of Paragraph 277.

COUNT II
STRICT LIABILITY – DESIGN AND/OR MANUFACTURING DEFECT

278. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 277 as if fully set forth herein.

279. Defendant denies the allegations of Paragraph 279.

280. Defendant denies the allegations of Paragraph 280.

281. Defendant admits that the devices were expected to reach Plaintiffs' treating physicians without substantial change in their condition. Defendant is without knowledge or information sufficient to admit or deny that the devices reached Plaintiffs without substantial change in their condition as manufactured and sold. Defendant denies the remaining allegations of Paragraph 281.

282. Defendant denies the allegations of Paragraph 282.

283. Defendant denies the allegations of Paragraph 283.

284. Defendant denies the allegations of Paragraph 284

285. Defendant denies the allegations of Paragraph 285.

286. Defendant denies the allegations of Paragraph 286.

COUNT III
NEGLIGENCE

287. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 286 as if fully set forth herein.

288. Defendant denies the allegations of Paragraph 288.

289. Defendant denies the allegations of Paragraph 289.

290. Defendant denies the allegations of Paragraph 290.

291. Defendant denies the allegations of Paragraph 291.

292. Defendant denies the allegations of Paragraph 292.

COUNT IV
NEGLIGENCE PER SE

293. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 292 as if fully set forth herein.

294. Paragraph 294 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal obligations and duties and denies the allegations of Paragraph 294.

295. Defendant denies the allegations of Paragraph 295.

296. Paragraph 296 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of Paragraph 296.

297. Defendant denies the allegations of Paragraph 297.

COUNT V
BREACH OF IMPLIED WARRANTY

298. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 297 as if fully set forth herein.

299. Defendant denies the allegations of Paragraph 299.

300. Defendant denies the allegations of Paragraph 300.

301. Defendant denies the allegations of Paragraph 301.

302. Defendant denies the allegations of Paragraph 302.

303. Defendant denies the allegations of Paragraph 303.

COUNT VI
FRAUD

304. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 303 as if fully set forth herein.

305. Defendant denies the allegations of Paragraph 305.

306. Defendant denies the allegations of Paragraph 306.

307. Paragraph 307 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal duties and denies the allegations of Paragraph 307.

308. Defendant denies the allegations of Paragraph 308.

309. Defendant denies the allegations of Paragraph 309.

COUNT VII
CONSTRUCTIVE FRAUD

310. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 309 as if fully set forth herein.

311. Defendant denies the allegations of Paragraph 311.

312. Defendant denies the conduct alleged and denies the remaining allegations of Paragraph 312.

313. Defendant denies the allegations of Paragraph 313.

314. Defendant denies the allegations of Paragraph 314.

315. Defendant denies the allegations of Paragraph 315.

COUNT VIII
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

316. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 315 as if fully set forth herein.

317. Paragraph 317 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal duties and denies the allegations of Paragraph 317.

318. Defendant denies the allegations of Paragraph 318.

319. Defendant denies the allegations of Paragraph 319.

320. Defendant denies the allegations of Paragraph 320.

321. Defendant denies the allegations of Paragraph 321.

322. Defendant denies the allegations of Paragraph 322.

323. Defendant denies the allegations of Paragraph 323.

324. Defendant denies the allegations of Paragraph 324.

325. Defendant denies the allegations of Paragraph 325.

326. Defendant denies the allegations of Paragraph 326.

COUNT IX
THE SENIOR CITIZEN AND HANDICAPPED PERSON CONSUMER FRAUD ACT
MINNESOTA STATUTE § 235F.71 AND/OR SIMILAR STATUTES IN EFFECT
IN OTHER JURISDICTIONS

327. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 326 as if fully set forth herein.

328. Paragraph 328 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that Paragraph 328 refers to and purports to

characterize and/or paraphrase a section of the Minnesota statutes. Defendant states that the complete and precise content of the statute can be ascertained from the statute itself.

329. Paragraph 329 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant admits that Paragraph 329 refers to and purports to characterize and/or paraphrase sections of the Minnesota statutes. Defendant states that the complete and precise content of the statutes can be ascertained from the statutes themselves.

330. Defendant denies the allegations of Paragraph 330.

331. Defendant denies the allegations of Paragraph 331.

332. Defendant denies the allegations of Paragraph 332.

333. Defendant denies the allegations of Paragraph 333.

334. Defendant denies the allegations of Paragraph 334.

335. Defendant denies the allegations of Paragraph 335.

336. Defendant denies the allegations of Paragraph 336.

337. Defendant denies the allegations of Paragraph 337.

338. Defendant denies the allegations of Paragraph 338.

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

339. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 338 as if fully set forth herein.

340. Defendant denies the allegations of Paragraph 340.

341. Paragraph 341 asserts legal conclusions to which no response is required. To the extent a response is required, Defendant states that it has complied with all applicable legal duties and denies the allegations of Paragraph 341.

342. Defendant denies the allegations of Paragraph 342.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

343. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 342 as if fully set forth herein.

344. Defendant denies the allegations of Paragraph 344.

345. Defendant denies the allegations of Paragraph 345.

346. Defendant denies the allegations of Paragraph 346.

347. Defendant denies the allegations of Paragraph 347.

COUNT XII
GROSS NEGLIGENCE/MALICE

348. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 347 as if fully set forth herein.

349. Defendant denies the conduct alleged, denies that Plaintiffs are entitled to exemplary damages or to any relief whatsoever, and denies the remaining allegations of Paragraph 349.

350. Defendant denies the conduct alleged, denies that Plaintiffs are entitled to exemplary damages or to any relief whatsoever, and denies the remaining allegations of Paragraph 350.

COUNT XIII
LOSS OF CONSORTIUM

351. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 350 as if fully set forth herein.

352. The allegations of Paragraph 352 are so nonsensical that Defendant is unable to provide a meaningful response. To the extent a response is required, Defendant denies the allegations of Paragraph 352.

353. Defendant denies the conduct alleged. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 353 and, therefore, denies the same.

354. Defendant denies that it is liable for the injuries alleged in Paragraph 354. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 354 and, therefore, denies the same.

355. Defendant denies that it is liable for the injuries alleged in Paragraph 355. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 355 and, therefore, denies the same.

356. Defendant denies that it is liable for the injuries alleged in Paragraph 356. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 356 and, therefore, denies the same.

357. Defendant denies the allegations of Paragraph 357.

COUNT XIV
WRONGFUL DEATH

358. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 357 as if fully set forth herein.

359. Defendant denies the allegations of Paragraph 359.

360. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 360 and, therefore, denies the same.

361. Defendant denies the allegations of Paragraph 361.

362. Defendant denies that Plaintiffs are entitled to any relief whatsoever. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 362 and, therefore, denies the same.

363. Defendant denies that Plaintiffs are entitled to the relief sought in Paragraph 363 or to any relief whatsoever.

COUNT XV
SURVIVAL ACTION

364. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 363 as if fully set forth herein.

365. Defendant denies the allegations of Paragraph 365.

366. Defendant denies that Plaintiffs are entitled to any relief whatsoever. Defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 366 and, therefore, denies the same.

367. Defendant denies that Plaintiffs are entitled to the relief sought in Paragraph 367 or to any relief whatsoever.

COUNT XVI
MEDICAL MONITORING

368. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 367 as if fully set forth herein.

369. Defendant denies the allegations of Paragraph 369.

370. Defendant denies the allegations of Paragraph 370.

COUNT XVII
UNJUST ENRICHMENT

371. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 370 as if fully set forth herein.

372. Defendant denies the allegations of Paragraph 372.

373. Defendant denies the allegations of Paragraph 373.

374. Defendant denies the allegations of Paragraph 374.

CLAIMS FOR RELIEF
THIRD PARTY PAYOR PLAINTIFFS

375. Defendant states that the claims brought by the Third Party Payor Plaintiffs were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 375. To the extent a response is required, Defendant denies that the Third Party Payor Plaintiffs are entitled to any relief whatsoever.

COUNT XVIII
VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICES ACT

By Order of this Court dated April 16, 2007, Count XVIII, the claim which is predicated upon Paragraph Nos. 376 through 386, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 376 through 386. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XIX
VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

By Order of this Court dated April 16, 2007, Count XIX, the claim which is predicated upon Paragraph Nos. 387 through 392, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 387 through 392. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XX
VIOLATION OF MINNESOTA FALSE STATEMENTS IN ADVERTISING STATUTE

By Order of this Court dated April 16, 2007, Count XX, the claim which is predicated upon Paragraph Nos. 393 through 398, was dismissed by the Court and, therefore, no response is

required to the allegations of Paragraph Nos. 393 through 398. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXI
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

By Order of this Court dated April 16, 2007, Count XXI, the claim which is predicated upon Paragraph Nos. 399 through 411, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 399 through 411. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXII
SUBROGATION LIABILITY DETERMINATION

By Order of this Court dated April 16, 2007, Count XXII, the claim which is predicated upon Paragraph Nos. 412 through 418, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 412 through 418. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXIII
UNJUST ENRICHMENT

By Order of this Court dated April 16, 2007, Count XXIII, the claim which is predicated upon Paragraph Nos. 419 through 427, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 419 through 427. To the extent a response to these

Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXIV
BREACH OF IMPLIED WARRANTY

By Order of this Court dated April 16, 2007, Count XXIV, the claim which is predicated upon Paragraph Nos. 428 through 432, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 428 through 432. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXV
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

By Order of this Court dated April 16, 2007, Count XXV, the claim which is predicated upon Paragraph Nos. 433 through 436, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 433 through 436. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXVI
MISREPRESENTATION BY OMISSION

By Order of this Court dated April 16, 2007, Count XXVI, the claim which is predicated upon Paragraph Nos. 437 through 443, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 437 through 443. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these

Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

CLAIMS FOR RELIEF
MEDICARE SECONDARY PAYOR PLAINTIFFS

444. Defendant states that the claims brought by the Medicare Secondary Payor Plaintiffs were dismissed by Order of the Court dated April 16, 2007 and, therefore, no response is required to the allegations of Paragraph 444. To the extent a response is required, Defendant denies that the Medicare Secondary Payor Plaintiffs are entitled to any relief whatsoever.

COUNT XXVII
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS

By Order of this Court dated April 16, 2007, Count XXVII, the claim which is predicated upon Paragraph Nos. 445 through 448, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 445 through 448. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXVIII
LIABILITY AS FIRST-PARTY INSURER UNDER MSP: AGREEMENT TO PAY
MEDICAL COSTS

By Order of this Court dated April 16, 2007, Count XXVIII, the claim which is predicated upon Paragraph Nos. 449 through 455, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 449 through 455. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXIX

**LIABILITY AS FIRST PARTY INSURER UNDER MSP: PROVISIONS OF EXPRESS
AND IMPLIED WARRANTIES**

By Order of this Court dated April 16, 2007, Count XXIX, the claim which is predicated upon Paragraph Nos. 456 through 462, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 456 through 462. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXX
**LIABILITY AS THIRD PARTY INSURER UNDER MSP: LIABILITY AS HOLDER OF
A LIABILITY INSURANCE POLICY OR PLAN**

By Order of this Court dated April 16, 2007, Count XXX, the claim which is predicated upon Paragraph Nos. 463 through 470, was dismissed by the Court and, therefore, no response is required to the allegations of Paragraph Nos. 463 through 470. To the extent a response to these Paragraphs is required, Defendant denies any allegations of wrongdoing contained within these Paragraphs and denies that Plaintiffs have stated a valid claim against Defendant or are entitled to any relief whatsoever against Defendant.

COUNT XXXI
PUNITIVE DAMAGES

471. Defendant incorporates by reference its answers to the allegations of Paragraphs 1 through 470 as if fully set forth herein.

472. Defendant denies that Plaintiffs are entitled to punitive and/or exemplary damages or to any relief whatsoever and denies the remaining allegations of Paragraph 472.

Defendant denies that Plaintiffs are entitled to the relief requested in the Prayer for Relief or to any relief whatsoever.

AFFIRMATIVE AND OTHER DEFENSES

Having answered the allegations of the Plaintiffs' First Amended Master Complaint and having denied any liability whatsoever, Defendant further denies any allegations that have not been expressly admitted and asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

The devices to which Plaintiffs refer in the Master Complaint are Class 3 prescription medical products. The federal government has preempted the field of law applicable to the design, testing, and labeling of prescription medical products. Plaintiffs' cause of action, therefore, fails to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

SECOND AFFIRMATIVE DEFENSE

At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and the state-of-the-art in existence at the time.

THIRD AFFIRMATIVE DEFENSE

The devices at issue in this case are prescription medical products that fall within the "comment k" and "comment j" exceptions to strict liability, as defined in Restatement (Second) of Torts §402A. The benefits of the devices outweigh the risks, if any, which may be attendant to their use. The devices are therefore neither defective nor unreasonably dangerous.

FOURTH AFFIRMATIVE DEFENSE

The devices at issue in this case are prescription medical products that fall within Restatement Third, Torts: Products Liability § 6. Therefore, the devices are reasonably safe in design if a reasonable healthcare provider would prescribe the devices for any class of patients knowing the foreseeable risks and therapeutic benefits.

FIFTH AFFIRMATIVE DEFENSE

Under the learned intermediary defense, the manufacturer of a prescription medical device is to provide warnings and appropriate information only to the prescribing physician and the medical profession, which act as “learned intermediaries” in determining the use of the product for a particular patient. To the extent Plaintiffs assert that Defendant failed to provide Plaintiffs with adequate warnings regarding the use of the device, any obligation to warn was discharged when adequate warnings were provided to Plaintiffs’ or Plaintiffs’ Decedents’ treating and prescribing physicians. Plaintiffs’ claims are also barred by the Sophisticated User Doctrine, or similar applicable laws.

SIXTH AFFIRMATIVE DEFENSE

Defendant believes, and upon that ground alleges, that Plaintiffs or Plaintiffs’ Decedents were advised of the risks associated with the matters alleged in Plaintiffs’ Master Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

SEVENTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, may have resulted from an intervening cause or causes, and any action on the part of Defendant was not the proximate or competent producing cause of Plaintiffs’ alleged injuries.

EIGHTH AFFIRMATIVE DEFENSE

The conduct of Defendant and the subject products conformed with the Federal Food, Drug, and Cosmetic Act and the requirements of the Food and Drug Administration. Moreover, Defendant's activities conformed with state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by the applicable statutes of limitations and statutes of repose.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by the doctrines of waiver, estoppel, and laches.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' breach of warranty claims are barred because there is no privity of contract between Plaintiffs and Defendant; Plaintiffs failed to give timely notice of any alleged breach of warranty to Defendant; Plaintiffs did not reasonably rely upon any alleged warranty; Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries occurred, if at all, because of circumstances and conditions beyond the control of Defendant.

FOURTEENTH AFFIRMATIVE DEFENSE

This action cannot be maintained as a class action because it does not meet the requirements to be certified as a valid class action set forth in Rule 23 of the Federal Rules of Civil Procedure and as further explained in the case law.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because any labeling with respect to the subject product was not false or misleading and, therefore, constitutes protected commercial speech under the applicable provisions of the United States Constitution and the Constitutions of the 50 states.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution because they purport to regulate interstate commerce and impermissibly place an undue burden on interstate commerce.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to satisfaction under the consumer protection laws of Minnesota or any other state because Plaintiffs cannot satisfy the elements of these statutes and because Plaintiffs lack standing to assert claims under these statutes.

NINETEENTH AFFIRMATIVE DEFENSE

While denying at all times that Plaintiffs have stated a valid claim under Minnesota consumer protection statutes or the consumer protection statutes of any other state, to the extent such claims are found to exist, Defendant pleads all defenses available under those statutes and states that any such claims are limited by the provisions of the statutes.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims fail to state a cause of action and fail to state claims for which relief may be granted.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The claims asserted in the Complaint are barred, in whole or in part, because the utility of the device at issue outweighs the alleged risk.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Defendant is entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other person or entity.

TWENTY-THIRD AFFIRMATIVE DEFENSE

To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendant's rights under the United States Constitution and analogous provisions of Constitutions of the 50 states.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

At all relevant times, herein, Plaintiffs' or Plaintiffs' Decedents' prescribing physicians were in the position of a sophisticated purchaser, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for fraud are barred because Plaintiffs have failed to specifically aver such claims as required by Federal Rule of Civil Procedure 9(b).

TWENTY-SIXTH AFFIRMATIVE DEFENSE

No act or omission of Defendant was malicious, willful, wanton, reckless, grossly negligent, or intentional and, therefore, any award of punitive damages is barred.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Punitive damages are not appropriate in this case and any claim for punitive damages contravenes the rights of Defendant under each of the following constitutional provisions: the Due Process Clause and the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Equal Protection Clause and Due Process Clause of the Fourteenth Amendment of the United States Constitution; the Constitutions of the 50 states; and the law, statutes, rules and policies of the 50 states given the circumstances of this litigation, including but not limited to:

- (a) imposition of punitive damages by a jury which
 - (1) is not provided with standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award;
 - (2) is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment;
 - (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, or state of residence of Defendant;

(4) is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; and

(5) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards;

(b) imposition of such punitive damages, and determination of the amount of an award thereof, where applicable state law is impermissibly vague, imprecise, or inconsistent;

(c) imposition of such punitive damages, and determination of the amount of an award thereof, without bifurcating the trial and trying all punitive damages issues only if and after the liability of Defendant has been found on the merits;

(d) imposition of such punitive damages, and determination of the amount of an award thereof, based on anything other than Defendant's conduct in connection with the sale of the products alleged in this litigation, or in any other way subjecting Defendant to impermissible multiple punishment for the same alleged wrong.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Any claim for punitive damages in this case cannot be sustained to the extent it seeks to punish Defendant for alleged harm to non-parties and/or persons who are not before the Court. Imposition of punitive damages under such circumstances would violate Defendant's procedural and substantive due process rights and equal protection rights under the Fifth and Fourteenth Amendments to the United States Constitution and Defendant's due process and equal protection

rights under cognate provisions of the Constitutions of the 50 states, and would be improper under the common law and public policies of the United States and the 50 states.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because equitable relief is not available under any of the alleged causes of action.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because Plaintiffs have an adequate remedy at law.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Complaint because the hardship that would be imposed on Defendant by the relief is greatly disproportionate to any hardship that Plaintiffs might suffer in its absence.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Complaint because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Defendant expressly reserves the right to amend this Answer to assert additional defenses or to make additional claims for relief as discovery in this action should warrant.

JURY DEMAND

Defendant hereby requests a jury trial as to all claims triable in this action.

PRAYER FOR RELIEF

WHEREFORE, Defendant prays for relief from judgment from Plaintiffs as follows:

1. Plaintiffs take nothing by reason of this Master Complaint;
2. Defendant recovers its costs, and attorneys' fees incurred herein;
3. For a trial by jury on all issues so triable; and
4. For such further and other relief as the Court deems proper.

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By: /s/ Timothy A. Pratt

Timothy A. Pratt

Missouri Bar No. 47454

2555 Grand Blvd

Kansas City, Missouri 64108-2613

Telephone: 816.474.6550

Facsimile: 816.421.5547

Joseph M. Price

FAEGRE & BENSON

2200 Wells Fargo Center

90 South Seventh Street

Minneapolis, Minnesota 55402-3901

Telephone: 612-766-7000

Facsimile: 612-766-1600

ATTORNEYS FOR DEFENDANT
GUIDANT SALES CORPORATION.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

Plaintiffs,

-against-

GUIDANT CORPORATION, GUIDANT SALES
CORPORATION, BOSTON SCIENTIFIC
CORPORATION, MICHAEL LIOU, M.D., BETH ISRAEL
MEDICAL CENTER AND BETH ISRAEL MEDICAL
CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants,
-----X

**AFFIDAVIT OF SERVICE
FOR SUMMONS &
VERIFIED COMPLAINT**


Index No.: 114306/07

Annexed hereto please find the following:

1. Affidavit of John Dicanio, indicating that on November 2, 2007 at 7:05 AM he served a copy of the **Summons, Verified Complaint and Certificate of Merit** upon **Dr. Michael Liou, M.D.**, located at **343 East 30th Street, New York, New York (Lobby)**, by delivering thereat a true copy to said defendant personally, deponent knew the person so served to be the person described as said defendant therein. He was approximately 21 to 35 years of age, approximately 160 pounds, approximately 5'9", with yellow skin and black hair.

Dated: Brooklyn, New York
November 5, 2007

I have read the foregoing Affidavit of Service for the Summons and Verified Complaint and I certify that, upon information and belief, the source of which is the review of a file maintained by my office, that the foregoing Affidavit of Service is not frivolous as defined in subsection (c) of Section 130-1.1 of the rules of the Chief Administrator.



ANDREA E. BONINA, ESQ.
BONINA & BONINA, P.C.
Attorneys for Plaintiff(s)
16 Court Street - Suite 1800
Brooklyn, NY 11241
718-522-1786

B 151— Affidavit of Service of Summons or Subpoena: Personal or Alternative
Methods: Corp. or Ind.; Military Service, 10 pt. type, 1-95

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SUPREME COURT OF THE STATE OF NEW YORK

COUNTY OF NEW YORK

SONIA URRIOLA,

Index No. 114306/07

Plaintiff(s)

against

GUIDANT CORPORATION, ET AL.,

Defendant(s)

**AFFIDAVIT OF
SERVICE OF SUMMONS
(AND COMPLAINT)**

VERIFIED

CERTIFICATE OF MERIT

STATE OF NEW YORK, COUNTY OF NEW YORK

SS: The undersigned, being duly sworn, deposes and says; deponent is not a

party herein, is over 18 years of age and resides at RYE BROOK, NEW YORK

That on 11/2/07

at 7:05 A.M., at 343 EAST 30TH STREET, NEW YORK, NEW YORK (LOBBY)

deponent served the within summons, and complaint on

MICHAEL LIOU, M.D.

defendant therein named,

VERIFIED, CERTIFICATE OF MERIT

INDIVIDUAL

1. ☒

by delivering a true copy of each to said defendant personally; deponent knew the person so served to be the person described as said defendant therein.

CORPORATION

2. ☐

a corporation, by delivering thereat a true copy of each to personally, deponent knew said corporation so served to be the corporation described in said summons as said defendant and knew said individual to be thereof.

SUITABLE AGE PERSON

3. ☐

by delivering thereat a true copy of each to a person of suitable age and discretion. Said premises is defendant's—actual place of business—dwelling place—usual place of abode—within the state.

AFFIXING TO DOOR, ETC.

4. ☐

by affixing a true copy of each to the door of said premises, which is defendant's—actual place of business—dwelling place—usual place of abode—within the state. Deponent was unable, with due diligence to find defendant or a person of suitable age and discretion thereat, having called there

**MAILING TO
RESIDENCE
USE WITH 3 OR 4**

5A. ☐

Within 20 days of such delivery or affixing, deponent enclosed a copy of same in a postpaid envelope properly addressed to defendant at defendant's last known residence, at and deposited said envelope in an official depository under the exclusive care and custody of the U.S. Postal Service within New York State.

**MAILING TO
BUSINESS
USE WITH 3 OR 4**

5B. ☐

Within 20 days of such delivery or affixing, deponent enclosed a copy of same in a first class post paid envelope properly addressed to defendant at defendant's actual place of business, at in an official depository under the exclusive care and custody of the U.S. Postal Service within New York State. The envelope bore the legend "Personal and Confidential" and did not indicate on the outside thereof, by return address or otherwise, that the communication was from an attorney or concerned an action against the defendant.

**DESCRIPTION
USE WITH
1, 2, OR 3**

☒

| | | | | | | |
|--|---|--|---|--|---|--|
| <input checked="" type="checkbox"/> Male | <input type="checkbox"/> White Skin | <input checked="" type="checkbox"/> Black Hair | <input type="checkbox"/> White Hair | <input type="checkbox"/> 14-20 Yrs. | <input type="checkbox"/> Under 5' | <input type="checkbox"/> Under 100 Lbs. |
| <input type="checkbox"/> Female | <input type="checkbox"/> Black Skin | <input type="checkbox"/> Brown Hair | <input type="checkbox"/> Balding | <input checked="" type="checkbox"/> 21-35 Yrs. | <input type="checkbox"/> 5'0"-5'3" | <input type="checkbox"/> 100-130 Lbs. |
| | <input checked="" type="checkbox"/> Yellow Skin | <input type="checkbox"/> Blonde Hair | <input type="checkbox"/> Mustache | <input type="checkbox"/> 36-50 Yrs. | <input type="checkbox"/> 5'4"-5'8" | <input checked="" type="checkbox"/> 131-160 Lbs. |
| | <input type="checkbox"/> Brown Skin | <input type="checkbox"/> Gray Hair | <input type="checkbox"/> Beard | <input type="checkbox"/> 51-65 Yrs. | <input checked="" type="checkbox"/> 5'9"-6'0" | <input type="checkbox"/> 161-200 Lbs. |
| | <input type="checkbox"/> Red Skin | <input type="checkbox"/> Red Hair | <input checked="" type="checkbox"/> Glasses | <input type="checkbox"/> Over 65 Yrs. | <input type="checkbox"/> Over 6' | <input type="checkbox"/> Over 200 Lbs. |

Other identifying features:

**USE IN
NYC CIVIL CT.**

☐

The words "CONSUMER CREDIT TRANSACTION" were prominently displayed at the top of the summons(es) and the additional legend was printed in not less than 12 point bold upper case type on the summons(es) pursuant to 22 NYCRR §208.6(d) and (f).

**MILITARY
SERVICE**

☒

I asked the person spoken to whether recipient was in active military service of the United States or of the State of New York in any capacity whatever and received a negative reply. Recipient wore ordinary civilian clothes and no military uniform. The source of my information and the grounds of my belief are the conversations and observations above narrated. Upon information and belief I aver that the recipient is not in military service of New York State or of the United States as that term is defined in either the State or in the Federal statutes.

Sworn to before me on
11/2/07

IRVING BOTWINICK
Notary Public, State of New York
No. 01804657147
Qualified in Rockland County
Commission Expires Oct. 31, 2009

PRINT NAME (WITH SIGNATURE)

JOHN DICANIO

License No. 775208

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SONIA URRIOLA,

Plaintiffs,

-against-

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON SCIENTIFIC CORPORATION, MICHAEL LIU, M.D., BETH ISRAEL MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants,

**AFFIDAVIT OF SERVICE FOR SUMMONS
AND VERIFIED COMPLAINT**

BONINA & BONINA, P.C.

Attorneys for *Plaintiff(s)*
16 Court Street, Suite 1800
Brooklyn, NY 11241
Tele. No.: (718) 522-1786
Fax No.: (718) 243-0414

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed documents are not frivolous.

Dated: **NOVEMBER 5, 2007**

Signature

Print Signer's Name:


ANDREA E. BONINA, ESQ.

Service of a copy of the within

is hereby admitted.

Dated:

Attorney(s) for

PLEASE TAKE NOTICE

Check Applicable Box

☐ **NOTICE OF ENTRY** *that the within is a (certified) true copy of a entered in the office of the clerk of the within named Court on*

☐ **NOTICE OF SETTLEMENT** *that a of which the within is a true copy will be presented for settlement to the Hon. , one of the judges of the within named Court, at Supreme, on ,*

Dated:

BONINA & BONINA, P.C.
Attorneys for *Plaintiff(s)*
16 COURT STREET
BROOKLYN, N.Y. 11241

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

Plaintiff,

-against-

GUIDANT CORPORATION, GUIDANT
SALES CORPORATION, BOSTON SCIENTIFIC
CORPORATION, MICHAEL LIU, M.D., BETH
ISRAEL MEDICAL CENTER and BETH ISRAEL
MEDICAL CENTER PHILIPS AMBULATORY
CARE CENTER,

Defendants,
-----X

**AFFIDAVIT OF SERVICE
OF THE SUMMONS AND
VERIFIED COMPLAINT**

Index No.: 114306/07

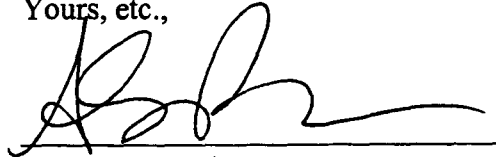
Annexed hereto please find the following:

- 1) Affidavit of DEPUTY SHERIFF SHOUA THAO of the Ramsey County Sheriff's Office indicating that on October 30, 2007 at he served a copy of the SUMMONS and VERIFIED COMPLAINT upon GUIDANT CORPORATION, 4100 Hamline Avenue North, St. Paul, Minnesota 55112 via SUSAN THOMPSON, Service Counsel, who was authorized to accept and over the age of 18 years.

Dated: Brooklyn, New York
November 7, 2007

"I have read the foregoing and I certify that, upon information and belief, the source of which is the review of a file maintained by my office, that the foregoing Affidavit of Service is not frivolous as defined in Subsection (c) of Section 130-1.1 of the Rules of the Chief Administrator."

Yours, etc.,

A handwritten signature in black ink, appearing to read 'A. Bonina', written over a horizontal line.

Andrea E. Bonina, Esq.
Bonina & Bonina, P.C.
Attorneys for Plaintiff
Sonia Urriola
16 Court Street - Suite 1800
Brooklyn, New York 11241
(718) 522-1786

STATE OF MINNESOTA

AFFIDAVIT OF SERVICE

COUNTY OF RAMSEY

I, Shoua Thao deposes and says: I am duly appointed, qualified and acting

Deputy Sheriff of said County of Ramsey, State of Minnesota, that the hereto

attached: SUMMONS & VERIFIED COMPLAINT

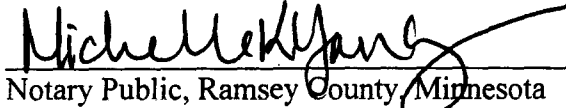
came into my hands for service on the 26th day of October, 2007 and at the City of St. Paul, County and State aforesaid, on the 30th day of October, 2007 I duly served the SUMMONS & VERIFIED COMPLAINT

here to attached upon the within GUIDANT CORPORATION, 4100 HAMLINE AVENUE NORTH, ST. PAUL, MN 55112 @ 1446

personally by then and there handing to and leaving with Susan Thompson, Service Counsel a true and correct copy thereof.

 168

Subscribed and sworn to before me, this 30th day of October, 2007


Notary Public, Ramsey County, Minnesota



Service Fees \$

Travel \$

Total \$

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK
SONIA URRIOLA,

Plaintiffs,

-against-

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON SCIENTIFIC CORPORATION, MICHAEL LIU, M.D., BETH ISRAEL MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants,

**AFFIDAVIT OF SERVICE FOR SUMMONS
AND VERIFIED COMPLAINT**

BONINA & BONINA, P.C.

Attorneys for *Plaintiff(s)*
16 Court Street, Suite 1800
Brooklyn, NY 11241
Tele. No.: (718) 522-1786
Fax No.: (718) 243-0414

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed documents are not frivolous.

Dated: November 7, 2007

Signature

Print Signer's Name:

ANDREA E. BONINA, ESQ.

Service of a copy of the within

is hereby admitted.

Dated:

Attorney(s) for

PLEASE TAKE NOTICE

Check Applicable Box

☐
NOTICE OF
ENTRY

that the within is a (certified) true copy of a
entered in the office of the clerk of the within named Court on

☐
NOTICE OF
SETTLEMENT

that a of which the within is a true copy
will be presented for settlement to the Hon. , one of the judges of the
within named Court, at Supreme, on ,

Dated:

BONINA & BONINA, P.C.
Attorneys for *Plaintiff(s)*
16 COURT STREET
BROOKLYN, N.Y. 11241

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
SONIA URRIOLA,

Plaintiff,

-against-

**AFFIDAVIT OF SERVICE
OF THE SUMMONS AND
VERIFIED COMPLAINT**

Index No.: 114306/07

GUIDANT CORPORATION, GUIDANT
SALES CORPORATION, BOSTON SCIENTIFIC
CORPORATION, MICHAEL LIOU, M.D., BETH
ISRAEL MEDICAL CENTER and BETH ISRAEL
MEDICAL CENTER PHILIPS AMBULATORY
CARE CENTER,

Defendants,
-----X

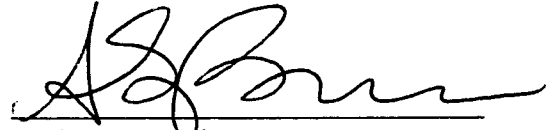
Annexed hereto please find the following:

- 1) Affidavit of VINCENT VANASCO indicating that on October 29, 2007 at 4:25 P.M., he attempted to serve a copy of the SUMMONS and VERIFIED COMPLAINT upon MICHAEL LIOU, M.D. c/o BETH ISRAEL MEDICAL CENTER, 307 1st Avenue, New York, New York 10003 but was informed that he no longer works for the hospital.
- 2) VINCENT VANASCO indicating that on October 29, 2007 at 4:25 P.M., he served a copy of the SUMMONS and VERIFIED COMPLAINT upon BETH ISRAEL MEDICAL CENTER, 307 1st Avenue, New York, New York 10003 via JILL DEVERY, Risk Management, who was authorized to accept and over the age of 18 years. She was a 36-50 year old female, 5'4"-5'8" in height, had white skin, blonde hair and was approximately 100-130 pounds.
- 3) VINCENT VANASCO indicating that on October 29, 2007 at 4:25 P.M., he served a copy of the SUMMONS and VERIFIED COMPLAINT upon BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CASE CENTER, 307 1st Avenue, New York, New York 10003 via JILL DEVERY, Risk Management, who was authorized to accept and over the age of 18 years. She was a 36-50 year old female, 5'4"-5'8" in height, had white skin, blonde hair and was approximately 100-130 pounds.

Dated: Brooklyn, New York
November 29, 2007

"I have read the foregoing and I certify that, upon information and belief, the source of which is the review of a file maintained by my office, that the foregoing Affidavit of Service is not frivolous as defined in Subsection (c) of Section 130-1.1 of the Rules of the Chief Administrator."

Yours, etc.,

A handwritten signature in black ink, appearing to read 'A. Bonina', written over a horizontal line.

Andrea E. Bonina, Esq.
Bonina & Bonina, P.C.
Attorneys for Plaintiff
Sonia Urriola
16 Court Street - Suite 1800
Brooklyn, New York 11241
(718) 522-1786

SONIA URRIOLA,

Plaintiff(s)

Index No.: 114306/07

against

Cal. No.:
AFFIDAVIT OF SERVICE

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON
SCIENTIFIC CORPORATION, MICHAEL LIOU, M.D. BETH ISREAL
MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS
AMBULATORY CARE CENTER,

Defendant(s)

STATE OF NEW YORK

COUNTY OF QUEENS

I, VINCENT VANASCO, being duly sworn, deposes and says; that he is not a party herein, is over the age of 18 years, and resides in the State of New York.
That on OCTOBER 29, 2007, at 4:25 P.M., at 307 1ST AVENUE NEW YORK, NEW YORK 10003
deponent attempted to serve the within

☒ SUMMONS ☐ WITH NOTICE
☐ SUMMONS AND COMPLAINT
☒ VERIFIED COMPLAINT
☐ SUBPOENA ☐ SUBPOENA DUCES TECUM

☐ ORDER TO SHOW CAUSE
☐ NOTICE TO TAKE ORAL DEPOSITION
☐ CITATION
☐ OTHER

on DR. MICHAEL LIOU C/O BETH ISREAL MEDICAL CENTER

☐ witness ☐ defendant ☐ plaintiff
☐ respondent ☐ petitioner

PERSONAL

- ☒ Based on our investigations, the party to be served is no longer at the given address.
☐ Based on our investigations, the party to be served is not listed on the building directory
☐ Based on our investigations, the address given does not exist
☐ Based on our investigations, the address given is an abandoned property
☐ Based on our investigations, the address given is a board up property
☐ Based on our investigations, the address given is a vacant lot

CORPORATION

- ☐ Based on our investigations, the party to be served is no longer at the given address.
☐ Based on our investigations, the party to be served is not listed on the building directory
☐ Based on our investigations, the address given does not exist
☐ Based on our investigations, the address given is an abandoned property
☐ Based on our investigations, the address given is a board up property
☐ Based on our investigations, the address given is a vacant lot


AFFIXING TO DOOR, ETC.

- ☐ Affixing a true copy in a conspicuous place at the owner's ☐ residence or ☐ place of business
☐ After having made a previous attempt of service at the above location on _____, 200____ at _____ a.m.; and _____, 200____ at _____ a.m.;
☐ By mailing, on _____, a true copy by first class mail addressed as follows: _____
☒ VERIFICATION: NO LONGER WORKS FOR THE HOSPITAL.

SWORN TO ME BEFORE THIS 29
DAY OF October, 2007

NOTARY PUBLIC

JOHN D. GIVENS JR.
COMMISSIONER OF DEEDS
City of New York - No. 4-5315
Qualified in Kings County
Commission Expires January 8, 2008


VINCENT J. VANASCO
LIC: 1265736

SONIA URRIOLA,

Plaintiff(s)

Index No.: 114306/07

against

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON
SCIENTIFIC CORPORATION, MICHAEL LIOU, M.D., BETH ISRAEL
MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS
AMBULATORY CARE CENTER,

Defendant(s)

Cal. No.:
AFFIDAVIT OF SERVICE

STATE OF NEW YORK
COUNTY OF QUEENS

I, VINCENT VANASCO, being duly sworn, deposes and says; that he is not a party herein, is over the age of 18 years, and resides in the State of New York.
That on OCTOBER 29, 2007, at 4:25 P.M., at 307 1ST AVENUE NEW YORK, NEW YORK 10003

deponent served the within

☒ SUMMONS ☐ WITH NOTICE
☐ SUMMONS AND COMPLAINT
☒ VERIFIED COMPLAINT
☐ SUBPOENA ☐ SUBPOENA DUCES TECUM

☐ ORDER TO SHOW CAUSE
☐ NOTICE TO TAKE ORAL DEPOSITION
☐ CITATION
☐ OTHER

on BETH ISREAL MEDICAL CENTER

☐ witness ☐ defendant ☐ plaintiff
☐ respondent ☐ petitioner

- ☐ Individual by delivering a true copy of each to said recipient personally; deponent knew the person so served to the person described as said recipient therein.
- ☒ Corporation a DOMESTIC corporation, by delivering thereat a true copy of each to JILL DEVERY personally, deponent knew said corporation so served to be the corporation, described in same as said recipient and knew said individual to be RISK MGMT thereof.
- ☐ Suitable Age Person by delivering thereat a true copy of each to a person of suitable age and discretion. Said premises is recipient's ☐ actual place of business ☐ dwelling place ☐ usual place of abode within the state.
- ☐ Affixing to Door, etc. by affixing a true copy of each to the door of said premises, which is recipient's ☐ actual place of business ☐ dwelling place ☐ usual place of abode within the state.
Deponent was unable, with due diligence to find recipient or a person of suitable age and discretion, thereat, having called there.
- ☐ Mailing to Residence Deponent talked to at said premises who stated that recipient ☐ lived ☐ worked there.
Within 20 days of such delivery or affixing, deponent enclosed a copy of same in a postpaid envelope properly addressed to recipient at recipient's last known residence, at and deposited said envelope in an official depository under exclusive care and custody of the U.S. Postal Service within New York State.
- ☐ Mailing to Business Within 20 days of such delivery or affixing, deponent enclosed a copy of same in a first class postpaid envelope properly addressed to recipient at recipient's actual place of business, at in an official depository under the exclusive care and custody of the U.S. Postal Service within New York State. The envelope bore the legend "Personal and Confidential" and did not indicate on the outside thereof, by return address or otherwise, that the communication was from an attorney or concerned an action against the recipient.

Deponent describes the person served as follows:

| | | | | | | |
|--|--|---|-------------------------------------|--|---|--|
| <input type="checkbox"/> Male | <input checked="" type="checkbox"/> White skin | <input type="checkbox"/> brown hair | <input type="checkbox"/> white hair | <input type="checkbox"/> 14-20 yrs. | <input type="checkbox"/> under 5' | <input type="checkbox"/> under 100 lbs. |
| <input checked="" type="checkbox"/> Female | <input type="checkbox"/> Black skin | <input type="checkbox"/> black hair | <input type="checkbox"/> balding | <input type="checkbox"/> 21-35 yrs. | <input type="checkbox"/> 5'0"-5'3" | <input checked="" type="checkbox"/> 100-130 lbs. |
| | <input type="checkbox"/> Yellow skin | <input checked="" type="checkbox"/> blonde hair | <input type="checkbox"/> mustache | <input checked="" type="checkbox"/> 36-50 yrs. | <input checked="" type="checkbox"/> 5'4"-5'8" | <input type="checkbox"/> 131-160 lbs. |
| | <input type="checkbox"/> Brown skin | <input type="checkbox"/> gray hair | <input type="checkbox"/> beard | <input type="checkbox"/> 51-65 yrs. | <input type="checkbox"/> 5'9"-6'0" | <input type="checkbox"/> 161-200 lbs. |
| | <input type="checkbox"/> Red skin | <input type="checkbox"/> red hair | <input type="checkbox"/> glasses | <input type="checkbox"/> over 65 yrs. | <input type="checkbox"/> over 6' | <input type="checkbox"/> over 200 lbs. |

Other identifying features:

☐ Witness Fees \$ the authorizing traveling expenses and one days' witness fee: ☐ was paid (tendered) to the recipient
☐ was mailed to the witness with subpoena copy.

☒ Military Service I asked the person spoken to whether recipient was in active military service of the United States or of the State of New York in any capacity whatever and received a negative reply. Recipient wore ordinary civilian and no military uniform. The sources of my information and the grounds of my belief are the conversations and observations above narrated.
Upon information and belief I aver that the recipient is not in military service of New York State or of the United States as that term is defined in either the State or in the Federal statutes.

Sworn to before me this 29 day of October 2007
JOHN D. GIVENS JR.
COMMISSIONER OF DEEDS
City of New York - No. 4-5315
Qualified in Kings County
Commission Expires January 6, 2008

VINCENT J. VANASCO
LIC: 1265736

SONIA URRIOLA,

Plaintiff(s)

Index No.: 114306/07

against

Cal. No.:
AFFIDAVIT OF SERVICE

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON
SCIENTIFIC CORPORATION, MICHAEL LIU, M.D., BETH ISRAEL
MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS
AMBULATORY CARE CENTER,

Defendant(s)

STATE OF NEW YORK
COUNTY OF QUEENS

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☐ witness ☐ defendant ☐ plaintiff
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Sworn to before me this 29 day of October, 2007
JOHN D. GIVENS JR.
COMMISSIONER OF DEEDS
(Notary Public or Commissioner of Deeds of New York - No. 45315
Qualified in Kings County
Commission Expires January 1, 2008

Vincent J. Vanasco
VINCENT J. VANASCO
LIC: 1265736

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

SONIA URRIOLA,

Plaintiff,

-against-

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, BOSTON SCIENTIFIC CORPORATION, MICHAEL LIOU, M.D., BETH ISRAEL MEDICAL CENTER AND BETH ISRAEL MEDICAL CENTER PHILIPS AMBULATORY CARE CENTER,

Defendants.

AFFIDAVIT OF SERVICE OF THE SUMMONS AND VERIFIED COMPLAINT

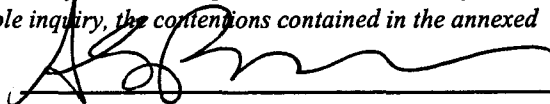
BONINA & BONINA, P.C.

Attorneys for *Plaintiff(s)*
16 Court Street, Suite 1800
Brooklyn, NY 11241
(718) 522-1786
Fax No.: (718) 243-0414

Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information and belief and reasonable inquiry, the contentions contained in the annexed documents are not frivolous.

Dated: November 29, 2007

Signature



Print Signer's Name: ANDREA E. BONINA, ESQ.

Service of a copy of the within

is hereby admitted.

Dated:

Attorney(s) for

PLEASE TAKE NOTICE

Check Applicable Box

☐ NOTICE OF ENTRY
that the within is a (certified) true copy of a
entered in the office of the clerk of the within named Court on

☐ NOTICE OF SETTLEMENT
that an Order of which the within is a true copy will be presented for settlement to the Hon.
one of the judges of the within named Court,
at on 20 , at M.

Dated:

BONINA & BONINA, P.C.

Attorneys for *Plaintiff(s)*
16 COURT STREET
BROOKLYN, N.Y. 11241

To:

Attorney(s) for